

Non-interventional study report

Study ID: NN7711-4729

Clinical outcomes of NovoSeven® treatment in severe postpartum haemorrhage – a retrospective single-centre cohort study at the University Hospital of Bern

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Title page

Title	Clinical outcomes of NovoSeven® treatment in severe postpartum haemorrhage – a retrospective single-centre cohort study at the University Hospital of Bern
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Procedure number	Not applicable
Marketing authorisation holder	Novo Nordisk A/S Novo Allé 2880 Bagsværd Denmark
Joint PASS	No
Research question and objectives	To compare, in a propensity score matched population of women with severe postpartum haemorrhage, the occurrence of any invasive procedure after first treatment with NovoSeven® with the occurrence of any invasive procedure without treatment with NovoSeven®. Invasive procedures were defined as uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures, or hysterectomy.
Country of study	Switzerland
Author	██████████, ██████████, Novo Nordisk A/S
UTN	U1111-1248-2816
ClinicalTrials.gov identifier	NCT04444856
IND number	Not applicable
Generic name	rFVIIa
Indication	Severe postpartum haemorrhage
Physicians	There were 3 physicians involved in the present study. The following 2 physicians were appointed as the signatory physicians for the study report: • ██████████, ██████████, Department of Obstetrics and Gynecology, University Hospital and University of Bern, Bern, Switzerland • ██████████, ██████████, Department of Obstetrics and Gynecology, University Hospital and University of Bern, Bern, Switzerland
Study initiated	29 June 2020
Study completed	13 January 2021
Report date	02 September 2021

Marketing authorisation holder

Marketing authorisation holder	Novo Nordisk A/S Novo Allé 2880 Bagsværd Denmark

This study was conducted in accordance with the Guidelines for Good Pharmacoepidemiology Practices.^{[1](#)}

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1 Abstract

Please refer to [separate document](#).

2 List of abbreviations and definitions of terms

I° CS	caesarean section before start of delivery, i.e., a planned caesarean section
II° CS	caesarean section performed after start of contractions or rupture of membranes
AIP	abnormally invasive placenta
ATE	arterial thromboembolic event
BMI	body mass index
CI	confidence interval
CS	caesarean section
DBL	database lock
EMA	European Medicines Agency
EU PAS	The European Union electronic register of post-authorisation studies maintained by the European Medicines Agency
FAS	full analysis set
FFP	fresh frozen plasma
HELLP	haemolysis, elevated liver enzymes and low platelets
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICU	intensive care unit
IEC	independent ethics committee
IQR	interquartile range
PACU	post anaesthesia care unit
PE	pulmonary embolism
PPH	postpartum haemorrhage
PS	propensity score
RBC	red blood cells
SAP	statistical analysis plan
t _d	time of delivery
t _i	time in minutes since time of onset of severe postpartum haemorrhage
TE	thromboembolic event
t _{sPPH}	time of onset of severe postpartum haemorrhage
TXA	tranexamic acid
UTN	universal trial number
VTE	venous thromboembolic event
WHO	World Health Organization

3 Physicians

There were 3 physicians, 1 study midwife and 1 PhD student involved in the collection of data in the present study. In the previously reported data from 2 historical cohorts and 1 study cohort (Section [9.1.1](#)), 8 additional physicians were involved.²

The following physicians were appointed as the signatory physicians for this non-interventional study report:

- [REDACTED], [REDACTED], Department of Obstetrics and Gynecology, University Hospital and University of Bern, Bern, Switzerland.
- [REDACTED], [REDACTED], Department of Obstetrics and Gynecology, University Hospital and University of Bern, Bern, Switzerland.

Contact details of all physicians involved in the collection of data in the present study are presented in [Annex 1](#), [Appendix 16.1.4](#).

4 Other responsible parties

Data collection was performed by the study physicians at the University Hospital of Bern, Switzerland. Pseudonymised/anonymised data were transferred to Novo Nordisk. All other study activities i.e. data management, data analysis and reporting were conducted in-house by Novo Nordisk.

5 Milestones

Table 5-1 Milestones

Milestone	Planned date	Actual date
Approval of protocol (version 1.0) ^a	08 May 2020	20 May 2020
Registration in the EU PAS Register	Not applicable	19 June 2020
Start of data collection for this study (first data transfer)	29 June 2020	29 June 2020
End of data collection for this study (last data transfer)	20 January 2021	13 January 2021
Approval (DBL) of PS model	Not applicable	17 June 2021
Final report of study results	01 May 2021	02 September 2021

^aApproval dates of protocol version 2.0 and 3.0 are provided in Section [8](#).

Abbreviations: DBL = database lock; EU = European Union; PAS = post-authorisation study; PS = propensity score

6 Rationale and background

6.1 Scientific background and rationale for study

Postpartum haemorrhage is typically defined as blood loss of at least 500 mL during vaginal delivery and 1000 mL during caesarean delivery.³ Severe PPH can be defined as continuous blood loss of at least 1500 mL within 24 hours following delivery.²

Complications following severe PPH are often critical and can include organ failure, TEs, haemorrhagic shock and death. These complications require interventions that can involve blood product transfusions, invasive procedures including emergency hysterectomy and admission to the intensive care unit.⁴

Emergency postpartum hysterectomy may be implemented in severe PPH, particularly when haemorrhage is uncontrollable and life-threatening.^{5,6} Such a serious intervention has profound implications including that women cannot get pregnant again. Consequently, it would be valuable to have an early, effective, non-invasive treatment for severe PPH that could reduce the need for hysterectomy and other invasive procedures. This would subsequently reduce maternal morbidity and aid in conserving the future reproductive potential of women.⁷

PPH is the leading preventable cause of maternal illness and death globally and there remains a significant unmet need to optimise the standard of care. The global incidences of PPH and severe PPH are estimated to be 6-11% and 1-3%, respectively, with substantial variations across regions.⁸ Worldwide, PPH accounts for 8% of maternal deaths in developed regions of the world and 20% of maternal deaths in developing regions.⁹

The current treatment options for PPH relate to the underlying cause of haemorrhage; a combination of pharmacological, blood product, mechanical and surgically related interventions are used; additionally, clinicians can consider the use of haemostatic agents including activated recombinant factor VII.^{10,11}

NovoSeven® is a recombinant FVIIa product developed by Novo Nordisk. It was authorised in Switzerland in December 1995 and in the EU in 1996 for the treatment of bleeding episodes and for the prevention of bleeding during surgery/invasive procedures in patients with certain haemostasis impairments¹² but is not currently approved for use in severe PPH. Nevertheless, treatment with NovoSeven® in women with severe PPH following uterotonic failure and prior to any invasive interventions has been suggested to control bleeding and prevent the need for hysterectomy.^{7,13,14}

NovoSeven® has a well-established safety profile from clinical trials and more than 25 years of post-marketing experience across multiple indications other than severe PPH. However, a relevant safety concern for the use of NovoSeven® in severe PPH is the risk of developing TEs due to a potential overstimulation of the coagulation system. In general, the incidence of TEs is higher in all parturients during the first 6 weeks after delivery, and factors such as caesarean-section, PPH or a BMI of >30 kg/m² may further increase the likelihood of TEs.¹⁵ The incidence of TEs has been reported to range from <1-7.8%¹⁶⁻¹⁸ in women with PPH in general and 2.5-4.8% in women with PPH treated off-label with NovoSeven®.^{14,19,20} In brief, the background incidence of TEs in women

with PPH is increased regardless of the use of NovoSeven®, however further clarifications are needed whether NovoSeven® may contribute an additional increase in TE risk in these women.

Novo Nordisk aims to develop a more comprehensive understanding of the clinical efficacy and safety of NovoSeven® usage in severe PPH by performing analyses of data available from clinical registries. In 2018, Colucci et al. published a single-centre study with data collected from medical records at the University Hospital of Bern, Switzerland.² The data consisted of 3 cohorts of women: 2 historical cohorts and 1 prospective study cohort. The first historical cohort consisted of data from women with severe PPH treated in the period 2006-2007 (followed in-house guideline on low-dose (60 µg/kg) NovoSeven®)²¹ and the second historical cohort consisted of data from women with severe PPH treated in the period 2008-2010 (followed no standard treatment protocol). The prospective study cohort consisted of women with severe PPH treated in the period 2010-2012 (followed a standard PPH management protocol).

In the study by Colucci et al., it was demonstrated that it is beneficial to use a standardised management protocol when treating severe PPH.² Furthermore, the study suggested that such a management protocol should include uterotonics and immediate administration of TXA, transfusion of RBCs, FFP and platelet concentrates, and thereafter administration of low-dose fibrinogen concentrate and NovoSeven®. These measures were shown to reduce blood product administration and rate of emergency hysterectomy in women with severe PPH. Of the 74 women included in the study, 1 (1.4%) woman from historical cohort 2, who did not receive NovoSeven®, TXA or fibrinogen, experienced a PE after delivery. There were no maternal deaths in the study. The authors concluded that early aggressive treatment of severe PPH with a coordinated multifunction team was the best option.²

The present study included data from the aforementioned 3 cohorts² and, additionally, a new cohort of women with severe PPH treated according to existing guidelines²² in the period 2013 to 2016. The data for the new cohort were collected retrospectively from electronic medical records. Additional information on timing of different interventions was also collected for the 3 published cohorts.²

Please refer to the study protocol in [Annex 1 \(Appendix 16.1.1\)](#) for a detailed description on the rationale and background of the study.

6.2 Ethics

The collection of data from patients' medical records for the period between 01 January 2006 and 30 April 2016 was approved by the local IEC ([Annex 1, Appendix 16.1.3](#)) before the collection of study data was initiated.

In the publication by Colucci et al.,² historical cohort 1 included 6 women who were included between 01 January 2005 and 31 December 2005. However, approval of data collection from historical cohort 1 was not available until 01 January 2006. Therefore, the data from these 6 women are not included in the present study. As described by Colucci et al.,² all 6 of these women received NovoSeven®; no TEs or maternal deaths were reported for these 6 women.

The current study was initiated voluntarily by Novo Nordisk and it was conducted in accordance with Good Pharmacoepidemiology Practices.¹ A checklist evaluating the suitability of the study,

based on EMA draft guideline for registry-based studies²³ is provided in [Annex 2](#), [Appendix 16.2.9.1](#).

6.3 Informed consent

According to applicable regulations, informed consent was not needed from the individuals prior to including their data in the study. The data in the database were pseudonymised/anonymised, i.e. the patients' records were kept under ID codes. No personal information which would enable identification of the person was collected.

7 Research question and objectives

As stated in the study protocol ([Annex 1](#), [Appendix 16.1.1](#)), the objectives of the study were as follows:

Primary objective:

- To compare, in a PS matched population of women with severe PPH, the occurrence of any invasive procedure after first treatment with NovoSeven® with the occurrence of any invasive procedure without treatment with NovoSeven®.
Invasive procedures were defined as uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures or hysterectomy.

Estimand

The estimand addressed the relative effect of NovoSeven® compared to PS matched controls on the occurrence of invasive procedures in women with severe PPH.

The estimand was defined from the following 5 elements outlined in the ICH E9(R1):

- The treatment conditions were NovoSeven® versus PS matched controls.
- The treatment effect was estimated for women with severe PPH defined by the inclusion criteria in the 4 cohorts exposed to NovoSeven® and their matched controls.
- The treatment effect was assessed by the occurrence of invasive procedures within 20 minutes to 24 hours following time0.
- Intercurrent events were handled by a hypothetical strategy or a treatment policy strategy (further details in [Table 7-1](#)).
- The treatment effect was quantified by the conditional odds ratio.

Table 7-1 Handling of intercurrent events for the hypothetical estimand

Intercurrent event	Expected frequency of events	Data collection and analysis
Death	Rare	Death within the time window for the primary endpoint was counted as having an invasive procedure
Exposure to NovoSeven® after time0	Likely	In case a matched control was exposed to NovoSeven® after the matching or an exposed woman had additional doses, this event was treated according to a treatment policy strategy, i.e. these intercurrent events were ignored in the statistical analysis

Timescale for matching was time (in hours and minutes) since onset of severe PPH.

For exposed women: time0 was defined as time of first administration of NovoSeven®. It occurred 'x' minutes after onset of severe PPH.

For matched controls: time0 was derived from the matching process. It was equal to the period from onset of severe PPH to time of first administration of NovoSeven® for the woman for whom she was a matched control.

A lag-time of 20 minutes was implemented based on inputs from experts within this area:

- The 20-minute lag-time was chosen to disregard any case where a conjoint decision had been taken to administer NovoSeven® and perform an invasive procedure consecutively.
- It would take 10 minutes for NovoSeven® to reach peak coagulation ability.²⁴
- For cases where the decision to perform an invasive procedure was taken simultaneously with administration of NovoSeven®, NovoSeven® would not have had sufficient time to be effective. Thus, if a procedure was performed within the lag time, this should not be considered as lack of efficacy of NovoSeven®.

The influence of the “20-minute lag window” was evaluated by supportive endpoints with different options for the time gap, see Section [9.9.4.1.6](#).

The handling of intercurrent events was chosen for the following reason:

- If a woman died within 24 hours after matching without the performance of an invasive procedure, the death was considered possibly related to the PPH condition and it was assumed that the lack of any invasive procedures performed was due to lack of time. Thus, the woman was in a condition where performance of an invasive procedure would be highly relevant.

In the way intercurrent event of death was handled, plausibly explicit assumptions of what would have happened if this had not occurred were made. Therefore, a hypothetical strategy was used to handle intercurrent events of death. As explicit values were assigned to the primary endpoint the same end result could also have been obtained via a composite endpoint strategy.

If a matched control was exposed to NovoSeven® after the matching time0, this was ignored following the treatment policy strategy. Any imputation with event in some or all such cases would bias the results under the null hypothesis. Under the alternative hypothesis that NovoSeven® had a positive effect this approach would bias the results towards null. A supportive analysis was conducted where controls with exposure to NovoSeven® after time0 without an event of the primary endpoint were imputed to also have event (see Section [9.9.4.1.5](#)). This analysis served as a benchmark in the opposite direction.

Additional doses with NovoSeven® in the already exposed women were also ignored following the treatment policy strategy for the same reasons as above. If the null hypothesis was rejected the influence of additional doses would be explored and be part of the evaluation of an appropriate treatment recommendation. Details are provided in the SAP ([Annex 1](#), [Appendix 16.1.7](#)).

Secondary objectives:

- To compare frequency of TEs in women with an event of severe PPH treated with NovoSeven® versus women with an event of severe PPH not treated with NovoSeven®.
- To compare the relative reduction in blood transfusions in women with an event of severe PPH treated with NovoSeven® versus women with an event of severe PPH not treated with NovoSeven®.
- To compare the relative reduction in blood loss in women with an event of severe PPH treated with NovoSeven® versus women with an event of severe PPH not treated with NovoSeven®.

- To compare the incidence of hysterectomy in women with an event of severe PPH treated with NovoSeven® to the incidence of hysterectomy in women with an event of severe PPH not treated with NovoSeven®.

8 Amendments and updates

There were 2 amendments to the original study protocol (dated 20 May 2020) and the updates are summarised in [Table 8-1](#) and were incorporated into the protocol ([Annex 1](#), [Appendix 16.1.1](#)).

Table 8-1 Amendments to the NN7711-4729 study protocol

Protocol version	Date	Section of study protocol	Amendment or update	Reason
2.0	26 August 2020	4 Milestones	Updates of the milestones	Study delay
		6. Rationale and background	Editorial changes	Editorial changes
		7.2 Estimand	Editorial changes and inclusion of a rationale for the estimand.	Clarification of the estimand
		8.1.1 Endpoints	The 20-min window for evaluating invasive procedure (primary endpoint) and hysterectomy (secondary endpoint) was deleted as the time0 included the 20-min window.	This update was primarily technical and was made to ensure balance between NovoSeven® treated women and controls at the time of matching (time0).
		8.3 Variables	Clarification of variables	To better reflect the actual data collection.
		8.7.3.1 Analysis of primary endpoint	Clarification of the primary population	Based on input from PPH experts it became clear that the previously suggested definition of the primary population would result in a too small population for statistical analysis.
		8.7.3.2 Analysis of secondary endpoints	Clarification that analysis of secondary endpoint (control of bleeding) also included a comparison of post-time0 levels. Updates to methods and editorial changes.	To reflect changes to analysis of primary endpoint.
		8.9 Limitations of research methods	Editorial changes	Editorial changes
3.0	22 December 2020	7.1 Primary objective	Update of primary objective	The primary objective previously included the incidence of invasive procedures. However, the primary endpoint is measuring the occurrence of invasive procedures. Thus, the primary objective was updated from incidence to proportion.

Protocol version	Date	Section of study protocol	Amendment or update	Reason
		7.2 Estimand	Editorial changes due to the update of the primary endpoint. An explanation of the 20-min lag-time was added. "Discharge from hospital" was deleted from intercurrent events, instead considered as missing data issue for women discharged from hospital. This information was added to Section 8.7.3.1. Additional intercurrent event was added.	Due to the update of the primary endpoint. The intercurrent event was identified as a likely event and a clarification on how to handle it was added.
		8.1 Study design	The retrospective data collection period was updated from January 2005-April 2016 to January 2006-April 2016.	Ethics committee approval for data collection was received only for the period from January 2006-April 2016.
		8.1.1 Endpoints	The 20-min window for evaluating invasive procedure (primary endpoint) and hysterectomy (secondary endpoint) was added. The definition of time0 was updated.	This update was made to better reflect the clinical question "What is the effect of NovoSeven® 20 minutes after its administration (onwards) on invasive procedures", this could be done by the new definition of time0. The update of time0 was made to avoid immortal time bias from time of exposure to time of matching.
		8.7.3.2 Analysis of secondary endpoints	Addition of supportive analyses. It was also clarified that an exact conditional logistic regression model was to be used. The supportive analysis was to be done on the matched population.	To evaluate the impact of 20-min lag time in the primary endpoint, supportive analyses were included.
		8.8.1 Critical documents	Editorial changes: the text referring to 'informed consent' was deleted as the study does not involve informed consent process.	Editorial change
		10 Management and reporting of adverse events/ adverse reactions	The text was updated to reflect that as the study was based on data already collected in historical medical records, Individual Case Safety Report was not to be performed in the study.	This update was made to follow the standard operating procedure (Non-Interventional and epidemiological studies based on external databases and registries-Q110133) requirements for protocols.

9 Research methods

9.1 Study design

9.1.1 Overall design

This was a single-centre, retrospective non-interventional cohort study of women with severe PPH who were treated with NovoSeven® or other standard of care during the period of January 2006 to April 2016 ([Figure 9-1](#)). The present study included data from 4 cohorts of women with severe PPH. The data from 3 cohorts have already been published by Colucci et al.² and data from a new cohort were added.

Figure 9-1 Study design and planned number of women

Historical cohort 1 (Cohort 1)	Historical cohort 2 (Cohort 2)	Study cohort (Cohort 3)	New cohort (Cohort 4)
Planned $N_{\text{total}} = 20$ Planned $N_{\text{exp}} = 20$ 36 months 01 Jan 2006 to 31 Dec 2007	Planned $N_{\text{total}} = 27$ Planned $N_{\text{exp}} = 15$ 27 months 01 Jan 2008 to 31 Mar 2010	Planned $N_{\text{total}} = 27$ Planned $N_{\text{exp}} = 14$ 36 months 01 Apr 2010 to 31 Dec 2012	Planned $N_{\text{total}} = 150$ Planned $N_{\text{exp}} = 11$ 40 months 01 Jan 2013 to 30 Apr 2016
In-house guideline for low dose NovoSeven®	No standard treatment protocol	Standardised management protocol	Revised standardised management protocol

Notes: The naming of the first 3 cohorts refer to the names used in the publication by Colucci et al.² The names in parentheses are the names used in the results section of this report.

“Historical cohort 1” (cohort 1) included 6 women who were included before the local independent ethics committee approved that study; these data are therefore not included in the present study (actual $N_{\text{total}} = 14$ and actual $N_{\text{exp}} = 14$ for “historical cohort 1”).

The planned number of exposed women for “study cohort” (cohort 3) was 14 women, as reported in the publication by Colucci et al.² However, actual $N_{\text{exp}} = 15$ for this cohort.

The “new cohort” (cohort 4) was added in the present study (actual $N_{\text{total}} = 97$ and actual $N_{\text{exp}} = 8$).

Abbreviations: N_{total} = total number of women; N_{exp} = number of women exposed to NovoSeven®.

Information regarding patient characteristics, concomitant treatment and outcomes in women with severe PPH treated with NovoSeven® is usually limited in many countries. The current study therefore included a description of women with severe PPH treated with NovoSeven®, or other standard of care in each of the 4 cohorts. This also included an assessment of the comparability of the cohorts and the frequency of clinical outcomes in the study population. To aid in this assessment, a PS was calculated for each woman and used to match the women with severe PPH treated with NovoSeven® and those who were not treated with NovoSeven®.

9.1.2 Endpoints

The primary endpoint is presented in [Table 9-1](#) and the secondary endpoints are presented in [Table 9-2](#).

Table 9-1 Primary endpoint

Endpoint title	Time frame	Unit
Occurrence of invasive procedures ^a (yes/no)	20 minutes to 24 hours following time0	Count of women

Note: Timescale for matching was time (in hours and minutes) since onset of severe PPH. For exposed women: time0 was defined as time of first administration of NovoSeven®. It occurred 'x' minutes after onset of severe PPH. For matched controls: time0 was derived from the matching process. It was equal to the period from onset of severe PPH to time of first administration of NovoSeven® for the woman for whom she was a matched control.

^aInvasive procedures were defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures, or hysterectomy.

Table 9-2 Secondary endpoints

Endpoint title	Time frame	Unit
Occurrence of thromboembolic events (yes/no)	From time0 until 5 days after time0	Count of women
Amount of blood products transfused	From delivery to 24 hours after time0	Units
Estimated blood loss	From delivery to 24 hours after time0	mL
Occurrence of hysterectomy (yes/no)	20 minutes to 24 hours following time0 ^a	Count of women

Note: Timescale for matching was time (in hours and minutes) since onset of severe PPH. For exposed women: time0 was defined as time of first administration of NovoSeven®. It occurred 'x' minutes after onset of severe PPH. For matched controls: time0 was derived from the matching process. It was equal to the period from onset of severe PPH to time of first administration of NovoSeven® for the woman for whom she was a matched control.

^aIn the protocol the timeframe was defined as "24 hours following time0" but any hysterectomy occurring in the conjoint period was excluded from this analysis.

9.2 Setting

9.2.1 Location and period of data collection

The study was performed at the Department of Obstetrics and Gynecology, University Hospital and University of Bern, Bern, Switzerland. The women were admitted to Bern University Hospital during the specified study period for each cohort, either as the primary hospital or secondary hospital (transfer patients). The study is based on data already recorded in historical medical records. Data collection (extraction of data from historical medical records) was performed during the period 29 June 2020 to 13 January 2021.

9.2.2 Data collection

Data for the first 3 cohorts originated from the database collected by Colucci et al. as described in the publication.² In addition, data for women in the new cohort (cohort 4) were collected retrospectively from electronic medical records. Furthermore, for women included in the study published by Colucci et al.,² additional information on timing of different interventions was collected.

The medical records, including patient charts, anaesthesiology records and transfusion records of all women with severe PPH, were analysed for the clinical data of interest documented by the treating

physician(s) or nurse(s)/midwife(s). The data included in the study covered the period from time of diagnosis of severe PPH (including baseline data) until the end of hospitalisation. A data collection sheet was used to capture study specific data ([Annex 1](#), [Appendix 16.1.2](#)). The data were then entered into a dedicated database by study site staff at the University Hospital of Bern, Switzerland.

Novo Nordisk had no role in the extraction or processing of the data and no influence on the input to the database. Transfer of data to Novo Nordisk for analysis is described in [Section 9.8](#).

9.2.3 Treatment

The treatment of severe PPH in the 4 cohorts are briefly described below.

Historical cohort 1 (cohort 1): 01 January 2006 to 31 December 2007

In historical cohort 1, all women were treated with uterotonics, fluid management, RBC, FFP, and/or fibrinogen and platelet transfusion according to current practice.^{2,21} If massive bleeding persisted after transfusion of 8 RBCs and 4 units of FFP, all women received NovoSeven® at a dose of 60 µg/kg body weight, according to an in-house guideline for treatment of massive bleeding. If blood loss was still ongoing, a second NovoSeven® dose was given. If uncontrollable bleeding persisted after this second dose, hysterectomy was performed. Please refer to Appendix A of the study protocol ([Annex 1](#), [Appendix 16.1.1](#)) for further details.

In the publication by Colucci et al.,² historical cohort 1 included 6 women who were included between 01 January 2005 and 31 December 2005. However, the local IEC did not approve the study until 01 January 2006. The data from these 6 women are therefore not included in the present study. In the interest of the present study, it can be noted that there were no maternal deaths or TEs reported in the women in historical cohort 1.

Historical cohort 2 (cohort 2): 01 January 2008 to 31 March 2010

In historical cohort 2, no specific treatment guidelines were followed.² The decision whether and when to administer blood products and haemostatic agents (e.g. TXA, fibrinogen and NovoSeven®) was left to the discretion of individual team leaders.

Study cohort (cohort 3): 01 April 2010 to 31 December 2012

In the prospective study cohort, all women aged ≥18 years who developed severe PPH after vaginal delivery or caesarean section were treated according to a standardised management protocol depicted in Appendix A of the study protocol ([Annex 1](#), [Appendix 16.1.1](#)). Briefly, identification of PPH initiated the monitoring together with mechanical, and physiological measures to stimulate the uterine contraction.² Hereafter, pharmacological measures were followed including early administration of uterotonics, fluids, and TXA. If bleeding persisted, an “emergency package” containing 4 units of RBCs, 4 units of FFP, 1 platelet concentrate, 2 g of fibrinogen concentrate and NovoSeven® at a dose of 60 µg/kg body weight was given to the patient. Additional NovoSeven® was administered if bleeding persisted. Surgical interventions included the identification and repair of lower genital tract lesions, manual and instrumental uterine revision and curettage, uterine tamponade by a balloon catheter or by surgical towels, laparotomy and uterine compression sutures (B-Lynch or Pereira sutures, Hayman suture technique, square sutures) and uterine artery embolisation. More blood products could be given if bleeding persisted. After consulting a

haematologist, a third dose of NovoSeven® could be administered. If bleeding persisted, hysterectomy was performed.

New cohort (cohort 4): 01 January 2013 to 30 April 2016

In the new cohort, all women aged ≥ 18 years who developed severe PPH after vaginal delivery or caesarean section were treated according to the standardised management protocol referred to in Appendix A of the study protocol ([Annex 1](#), [Appendix 16.1.1](#)). Briefly, the treatment protocol was very similar to that for the study cohort; however, the suggested dose of NovoSeven® was changed to 90 µg/kg.

9.3 Patients

9.3.1 Inclusion criteria

As stated in the study protocol ([Annex 1](#), [Appendix 16.1.1](#)), the inclusion criteria of the study were as follows:

1. Females.
2. Severe PPH, defined as continuous bleeding of at least 1500 mL within 24 hours after delivery.^a
3. Inclusion in one of the 4 cohorts (historical cohort 1, historical cohort 2, study cohort and new cohort). The cohorts are described in Section [9.2.3](#).

To be included in the study population, all inclusion criteria had to be answered “yes”.

9.3.2 Exclusion criteria

None.

9.3.3 Removal of patients from therapy or assessment

It was not possible to withdraw from the study as data were already collected and were to be transferred pseudonymised/anonymised to Novo Nordisk for analysis. Furthermore, the study population had already been treated and could not withdraw.

9.3.4 Sources of patients

There were no study-specific visits. This was a retrospective study of women treated for severe PPH during standard clinical practice at the Department of Obstetrics and Gynecology, University Hospital and University of Bern, Bern, Switzerland during the period the 01 January 2006 to 30 April 2016. Data were extracted from patient charts, anaesthesiology records and transfusion records.

9.3.5 Methods of selection of patients

All women who fulfilled the inclusion criteria (Section [9.3.1](#)) were included in the current study.

^a The protocol stated that women with blood loss of more than 1500 mL within 24 hours after delivery were eligible for the study. However, women with blood loss of exactly or more than 1500 mL were included in the FAS. For women with missing times and volumes of blood loss, the missing values were imputed using documented business rules.

9.4 Variables

The variables collected from patient charts included:

- Maternal age intervals (<20, 21-25, 26-30, 31-35, 36-40, >40 years)
- Body weight (kg)
- Parity
- Gravidity
- Gestational age at birth (weeks)
- Estimated total blood loss (mL) until severe PPH stop, discharge from hospital or death
- Risk factors predisposing to PPH
- Mode of delivery (spontaneous vaginal, instrumental vaginal, I° CS, II° CS and emergency CS)
- Cause of PPH
- Infused non-blood product fluids (mL or units)
- Blood product replacement (mL or units)
- Medicinal and surgical treatments
- Duration of bleeding prior to administration of haemostatic agents, including NovoSeven® (minutes)
- Stay in ICU (yes/no)
- Length of hospitalisation after delivery (days)
- Postpartum hysterectomy (yes/no)
- TEs (yes/no), measured during the time of hospitalisations
- Death (yes/no), measure during the time of hospitalisations
- Cause of death

These variables were supplemented with time information of medical treatment, invasive procedure and transfusions. The supplementary information was extracted from electronic anaesthesiologist records and included:

- Time, name and dose of bolus drugs (including haemostatic agents and uterotonics)
- Time, name and dose of other drugs (p.o., rectal etc, including haemostatic agents and uterotonics)
- Time, name and volume of fluid expansion and transfusions
- Time and volume of blood loss
- Time and type of invasive procedures

9.5 Data sources and measurement

See Section [9.2.2](#).

9.6 Bias

As this was a non-interventional study, potential confounding factors could not be ruled out. Data collection reflected routine clinical practice rather than mandatory assessments at pre-specified time points, which may have had an impact on the amount of data and its interpretation.

A non-interventional study cannot replicate the design and results of a randomised clinical trial since neither randomisation nor a strict protocol of treatment and assessments are part of clinical

practice. This non-interventional study included a comparison to standard of care (comparative effectiveness). PPH severity as well as availability of treatment options/preferences of treating physician might have influenced the choice of treatment. This confounding by indication might have introduced differences between the groups regarding patient characteristics associated with the treatment choice, as well as the outcome. PS matching was performed to mitigate bias (see Section [9.9.4.1.1](#)).

The study could also have included information bias (potential measurement error of exposure (such as dose µg/kg and frequency) and outcomes (internal validity of outcomes such as procedure and data on estimated blood loss)).

Data were collected at different time periods which might have introduced confounders. As an example, the estimation of blood loss was collected more precisely in the study cohort (cohort 3) and new cohort (cohort 4) than in the historical cohorts (cohorts 1 and 2). In addition, there were differences across cohorts in how frequently TXA and NovoSeven® were used, depending on the treatment guideline for each cohort (Section [9.2.3](#)), which could also have introduced some confounders.

9.7 Study size

There was no formal power calculation and the study included all women at the study site who were eligible according to the inclusion criteria.

[Table 9-3](#) shows the expected number of women to be included in the data analyses (approximate numbers as planned in the protocol).

Table 9-3 Planned sample size per cohort

Cohort	Number of women with severe PPH treated with NovoSeven®	Number of women with severe PPH not treated with NovoSeven®	Total number women with severe PPH
Historical cohort 1 (cohort 1)	14 ^a	0	14
Historical cohort 2 (cohort 2)	15	12	27
Study cohort (cohort 3)	14 ^b	13	27
New cohort (cohort 4) ^c	11	139	150

^aHistorical cohort 1 (cohort 1) included 6 women who were included before the local IEC approved that study, these data are therefore not included in the present study. ^bThe planned number of exposed women for “study cohort” (cohort 3) was 14 women, as reported in the publication by Colucci et al.² However, actual number of exposed women was 15 for this cohort. ^cExact numbers of women for “new cohort” (cohort 4) were not known when the protocol was written; actual numbers were 8 women treated with NovoSeven®, 89 women not treated with NovoSeven® and 97 women in total.

Abbreviations: IEC = independent ethics committee; PPH = postpartum haemorrhage.

9.8 Data transformation

Collection of data was handled by the study site staff at the University Hospital of Bern, Switzerland. Novo Nordisk provided a data collection sheet to the study site for capture of study specific data ([Annex 1, Appendix 16.1.2](#)). Instructions for completion and correction of the data collection sheet were provided. The physician ensured that study specific data were entered in the data collection sheet according to agreed timelines and that data were complete and accurate.

Appropriate measures such as encryption and pseudonymisation/anonymisation were enforced to protect the identity of women when transmitting data, in all presentations and publications as required by local/regional/national requirements.

Microsoft SharePoint was used for data entry of the data to be transferred to Novo Nordisk; this included an integrated audit trail as agreed with Novo Nordisk prior to data collection. Quality control of entered data was performed according to predefined check points. By signing an affirmation statement, the physician confirmed that the information in the data collection sheet was complete and correct. If corrections were made by the physician's authorised staff after the date of the physician's signature on the affirmation statement, this had to be signed again by the physician, if necessary according to pre-defined check points with Novo Nordisk.

The data were then entered into a dedicated database by the study site staff and the pseudonymised/anonymised data were transferred to Novo Nordisk. Novo Nordisk data management team documented the data transfer in a data management plan. Questions to the data were verified with the respective physician, as applicable, by Novo Nordisk.

9.9 Statistical methods

9.9.1 General considerations

Evaluation of data was based upon descriptive statistics and statistical analysis, i.e. summary tables, listings, and figures. Descriptive statistics of categorical data were summarised by frequency tables while continuous data were summarised by mean, standard deviation, median (IQR), minimum and maximum value. For categorical data, a missing information category was added. IQR was presented as Q1 and Q3. Data for the matched controls in the PS analysis set were weighted/adjusted according to Section [9.9.4.1.1](#).

Results from the statistical analysis of confirmatory primary endpoint and secondary endpoints are generally presented by risk ratio estimates and two-sided 95% CIs with two-sided p-value. A significance level (alpha) of 0.05 was used. No multiplicity adjustment was required as the confirmatory analysis was based only on one primary endpoint (invasive procedures) in the population without hysterectomy before or conjoint with time0.

Outliers (data quality)

Outliers were analysed one by one. Outliers were treated and managed as missing data if there was an indication of implausible data. If there was no indication of implausible data, outliers were kept as true values. Categorisation of variables could be considered to accommodate the variability and stability of models.

Multiple measurements

Only first bleeding (PPH) episode was considered in the PS matching. For a woman with episode of rebleed, the data from the second episode were not included in the PS matching.

General definitions

- “Invasive procedures” were defined as uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures or hysterectomy.

- “Other invasive procedures” refer to invasive procedures excluding hysterectomy, i.e., defined as uterine or iliac artery ligation, radiological arterial embolisation and uterine compression sutures.
- The groups “hysterectomy”, “other invasive procedure(s)” and “hysterectomy and other invasive procedure(s)” were mutually exclusive, meaning that each woman could only be classified in one category.
- Myocardial infarction and cerebrovascular accident were categorised as ATEs. Deep vein thrombosis and PE were categorised as VTEs. Other types of TEs were categorised as either ATE or VTE by clinical evaluation documented in the DBL minutes.
- time0: time of first administration of NovoSeven®. It occurred x minutes after onset of severe PPH. For matched controls: time0 was derived from the matching process. It was equal to the period from onset of severe PPH to time of first administration of NovoSeven® for the woman for whom she was a matched control.
- t_d: time of delivery.
- t_{sPPH}: time of onset of severe PPH.
- t_i: time in minutes since t_{sPPH}; all measurements were made (or interpolated) for every minute from t_{sPPH} until end of PPH, discharge or time of death.
- Before conjoint period, in conjoint period and after conjoint period were defined as follows:
 - Before conjoint period: the period from start of severe PPH to <20 minutes before time0
 - In conjoint period: the period from ≥20 minutes before time0 and <20 minutes after time0
 - After conjoint period: the period from ≥20 minutes after time0 to ≤24 hours after time0

9.9.2 Analysis sets

The following analysis sets were defined in accordance with the ICH E9:

- FAS: defined as all women who met the inclusion criteria for the study, i.e., all women with severe PPH.
- PS analysis set: defined as the women in the FAS who were matched in the propensity scoring.
- Supplementary PS analysis set: defined as the PS analysis set excluding matched controls who were exposed to NovoSeven® after time0.

In general, descriptive statistics were presented for the following groups:

- FAS
 - Women exposed to NovoSeven®.
 - Women not exposed to NovoSeven®.
 - Total: all women.
- PS analysis set
 - Women exposed to NovoSeven® and matched to at least one control.
 - Matched controls.

For the PS analysis set it was possible that a woman could be selected as a control before the timepoint when she was exposed to NovoSeven®. In such a case, the woman could be counted in both groups, once as a control and later as an exposed case, both with separate values for time0. In the FAS the two groups were mutually exclusive.

9.9.3 Main summary measures

Please refer to the SAP ([Annex 1, Appendix 16.1.7](#)) for the complete list of variables and for definitions applied.

9.9.3.1 Baseline characteristics and demographics

The baseline characteristics and demographics were summarised for the FAS and PS analysis set using descriptive statistics (Section [9.9.1](#)). In addition, these characteristics are presented by exploratory subgroups (Section [9.9.4.3](#)).

Baseline was defined by time0 (for definition of time0 see Section [9.9.1](#)).

9.9.3.2 Dosing information: clinical use of NovoSeven®

The clinical use of NovoSeven® was summarised for women exposed to NovoSeven® for the FAS and PS analysis set using descriptive statistics (Section [9.9.1](#)). In addition, these characteristics are presented by exploratory subgroups (Section [9.9.4.3](#)), except for NovoSeven® doses expressed in mg unit.

9.9.3.3 Concomitant medications

The use of relevant concomitant medications was summarised for the FAS and PS analysis set using descriptive statistics (Section [9.9.1](#)). In addition, these characteristics are presented by exploratory subgroups (Section [9.9.4.3](#)).

9.9.3.4 Clinical outcomes

The following clinical outcomes were summarised for the FAS and PS analysis set using descriptive statistics (Section [9.9.1](#)). In addition, these characteristics are presented by exploratory subgroups (Section [9.9.4.3](#)).

- Stay in ICU or PACU, (yes/no, %) (no stay was considered where time at ICU = 0 and Time at PACU = 0).
- Summary statistics of length of stay (time at ICU or PACU) in ICU or PACU, (hours).
- Summary statistics of length of hospitalisation, (days).
- Proportion of women with hysterectomy, N (%), in conjoint period and after conjoint period.
- Proportion of women with other invasive procedure(s), N (%), in conjoint period and after conjoint period.
- Proportion of women with hysterectomy and other invasive procedure(s), N (%), in conjoint period and after conjoint period.
- Proportion of women with any invasive procedure(s), N (%), in conjoint period and after conjoint period.
- Descriptive summary statistics for fibrinogen level (g/L) for women with no fibrinogen dose given between laboratory assessment used as baseline value and time0.
- Proportion of women having fibrinogen levels <2 g/L or ≥2g/L with no fibrinogen dose given between laboratory assessment used as baseline value and time0, (%).
- Descriptive summary statistics for haemoglobin (g/L) of women with no RBC units given between laboratory assessment used as baseline value and time0.

- Descriptive summary statistics for pH of women with no crystalloids and colloids doses given between laboratory assessment used as baseline value and time0.
- Proportion of women having pH category (<7.2 or ≥ 7.2) with no crystalloids and colloids doses given between laboratory assessment used as baseline value and time0, (%).
- Descriptive summary statistics for platelets ($10^9/L$) of women with no platelets dose given between laboratory assessment used as baseline value and time0.
- Proportion of women having platelets category ($<50 \times 10^9/L$ or $\geq 50 \times 10^9/L$) with no platelets dose given between laboratory assessment used as baseline value and time0, (%).
- Summary statistics of bleeding duration, (minutes).
- Summary statistics of the transfusion from time0 to 24 hours after time0 (units), divided on packed cells, FFP, platelet and cryoprecipitate.
- Summary statistics of fluid replacement after time0 divided on crystalloids and colloids
- Proportion of deaths during hospitalisation, (yes/no, %).
- Proportion of women having laparotomy in conjoint period and after conjoint period (yes or no, %).
- Proportion of women having intrauterine balloon and other tamponade in conjoint period and after conjoint period, (yes/no, %).
- Proportion of women having placenta removal in conjoint period and after conjoint period, (yes/no, %).
- Summary statistics of duration of bleeding from onset of severe PPH to prior to first administration of each one of haemostatic agents (TXA, fibrinogen, NovoSeven®), (minutes).

9.9.3.5 Laboratory parameters

The laboratory parameters (fibrinogen, haemoglobin, platelets, pH and body temperature) were summarised for the FAS and PS analysis set at baseline and for the respective concomitant doses administered between laboratory assessment used as baseline value and time0.

The baseline value for the laboratory parameters for the summary table was chosen as the closest value before time0 with in time window of 60 minutes prior to time0.

9.9.3.6 Additional safety descriptions

Additional information was described for each woman with a fatal outcome (fatal case) or with a TE (TE case) as described in the SAP ([Annex 1](#), [Appendix 16.1.7](#)).

The proportion of women having TE was summarised (N, %), also TEs were summarised separately for ATEs and VTEs. The proportions of women having an event of allergic reaction, cardiac arrest and haemorrhagic shock were summarised (N, %).

Summaries of TEs, allergic reaction, cardiac arrest and haemorrhagic shock were reported for FAS until discharge from hospital.

9.9.4 Main statistical methods

9.9.4.1 Primary endpoint

The primary endpoint was occurrence of invasive procedures (i.e., uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures, or hysterectomy) during 20 minutes to 24 hours following time0. The primary objective was addressed using PS matching (Section [9.9.4.1.1](#)) to ensure exchangeability between women with severe PPH treated with NovoSeven® and those who were not.

9.9.4.1.1 Propensity score matching

It is assumed that women with more severe or more progressed PPH are more likely to receive NovoSeven®, which may confound the association of administration of NovoSeven® with maternal outcomes. The time from delivery to the onset of PPH and to different treatment options is individual with large variation across women. To overcome this, the primary objective of the study was addressed using PS matching^{25, 26} to ensure that the contrasted groups were similar in terms of severity of haemorrhage and other factors such as prior treatments for PPH.

Women were not eligible for PS matching if they had pre-planned hysterectomy, hysterectomy before severe PPH onset, NovoSeven® before severe PPH onset, and a few exceptional cases with insufficient data to map a time course. Remaining women were eligible for matching from onset of severe PPH until whatever came first of end of PPH, hysterectomy, NovoSeven® administration or death.

The PS reflected the estimated probability of being exposed to NovoSeven® during the course of severe PPH. Propensity scores for every woman with severe PPH were estimated from t_{sPPH} by a Cox proportional hazard regression model with NovoSeven® as the dependent variable. A hazard was calculated for each woman at risk for each minute following onset of severe PPH. Covariates associated with initiation of NovoSeven® were included in the model to calculate time dependent PS (see below). A time depending matching algorithm was applied to mimic the nature of a randomised clinical trial where patients were randomised at the time where NovoSeven® was relevant. No replacement of controls was done e.g. if a woman had been chosen as a matched control, she was not eligible to be a matched control again. However, if a woman was exposed to NovoSeven® at a later stage she was also included as an exposed woman. The steps for model selection are described in the SAP ([Annex 1](#), [Appendix 16.1.7](#)).

Before DBL for PS matching, all data for invasive procedures and laparotomy after first dose for all NovoSeven® exposed women were unavailable to the medical and biostatistical team for model selection. After DBL for PS matching, data were unmasked and study group decisions on imputation of the course of events were re-evaluated in the light of complete data. However, matching was unchanged.

Potential variables for the propensity score model

Characteristics considered to be potential variables for the association between use of NovoSeven® and the outcome or characteristics considered to be risk factors for the occurrence of the primary outcome measure alone were selected based on clinical reasoning and prior knowledge with the input from several experts within the field. The variables are listed below based on their priority,

where “1. Cumulative packed RBCs transfusion (units)” had the highest priority and “11. TXA (yes/no)” had the lowest priority.

1. Cumulative packed RBCs transfusion (mL): time varying and accumulated since first transfusion.
2. Cumulative estimated volume of blood loss (units): time varying and accumulated since first transfusion.
3. Number of previous invasive procedure including balloon (count): time varying and accumulated since delivery.
4. Cumulative FFP transfusion (mL): time varying and accumulated since first transfusion.
5. Total crystalloid/colloid (mL): time varying and accumulated since first transfusion.
6. Platelet transfusion (yes/no): time varying (“once yes stay yes”) since first transfusion.
7. Fibrinogen concentrate (yes/no): time varying (“once yes stay yes”) since first transfusion.
8. Pre-eclampsia/eclampsia/HELLP (yes/no): baseline.
9. Primary cause of PPH: baseline.
10. Sum of number of uterotonic doses (count): time varying since PPH onset. The number of uterotonics doses was counted across different types of uterotonics.
11. TXA (yes/no): time varying (“once yes stay yes”) since first transfusion.

For the PS matching process, 5 different modes of delivery were grouped into 2 categories: caesarean (I° CS, II° CS and emergency caesarean) and vaginal (instrumental vaginal and spontaneous vaginal) mode of delivery. A woman exposed to NovoSeven® was only matched to another woman with the same mode of delivery.

To counteract overfitting in development of the PS model, the following rules were applied in the following sequence:

- Do not include more than the top X parameters from the list of variables, where X = number of exposed women (eligible for matching) divided by 8.
- In case there were model fit issues (e.g., some parameters or their standard errors had extreme estimates) then the model with X variables was to be reduced accordingly, starting by removing the lowest priority variable.

Weighting of propensity score matched controls

The PS matching aimed to select up to 4 controls for each exposed woman. Systematic differences could occur regarding which woman had 4 controls available and which had fewer controls available. To avoid such potential unbalance between matched exposed and matched controls, the matched controls were weighted accordingly to the number of controls in each family cluster (matched exposed woman and her matched control(s)). Thus, if a woman had 4 controls each had weight $\frac{1}{4}$, if a woman had only 2 controls then each would have weight $\frac{1}{2}$, etc. This was applied to all summary statistics for the matched controls in the PS analysis set. A row indicates the number of actual patients and a second row indicates the number of weighted patients.

For further details about the PS matching, please refer to the SAP ([Annex 1, Appendix 16.1.7](#)) and the statistical documentation ([Annex 2, Appendix 16.2.9.3](#)).

Standardised bias

When using PS analysis, it is important to examine whether the model has been adequately specified. This involves comparing matched exposed women and their matched controls within the PS matched sample. To compare the characteristics of the women exposed to NovoSeven® and their matched controls, a comparison of the means of the covariates between these two groups was done by investigating standardised bias (the standardised difference).

The level of standardised bias across covariates of maximum 0.10 was the target. However, a slight deviation from the target was acceptable if a considerable number of variables were included in the model.

Interaction terms of covariates and time were included in the model if the matching did not minimise the bias lower than the threshold stipulated. The bias was assessed graphically including the balance before and after the matching. Please refer to statistical documentation ([Annex 2](#), [Appendix 16.2.9.3](#)) for methods of calculating standardised bias.

9.9.4.1.2 Primary analysis

If the PS matching described in Section [9.9.4.1.1](#) succeeded (defined as not noninformative and evaluated to have adequate overall fit), the primary endpoint was to be analysed as described in this section.

After matching, all women with a hysterectomy in the conjoint period (see Section [9.9.1](#) for definition) were to be excluded for analyses related to invasive procedures as these women were no longer at risk for other invasive procedures.

The occurrence of the primary endpoint (invasive procedures) within a timeframe of 20 minutes to 24 hours following time0 was described by summarising the number and percent of women with an event for each of the two groups. The superiority hypothesis test was defined by:

- H0: The two groups of PS matched women have the same occurrence of invasive procedures.
- Ha: The two groups of PS matched women have different occurrence of invasive procedures.

Superiority of NovoSeven® was confirmed if the null hypothesis was rejected and there was a lower proportion of women with invasive procedures in the group of matched exposed women compared to the group of matched controls.

The primary endpoint (invasive procedures) was compared between women who were exposed to NovoSeven® and matched controls in the PS analysis set, using an exact conditional logistic regression to calculate the odds ratio, with a 95% CI, with conditional meaning that the pairing of women based on the PS matching was taken into account. The test assessing the odds ratio was two-sided and assessed at the 5% significance level.

Discharge from the hospital within 24 hours following matching, without an invasive procedure in the same time frame, was handled as incomplete data. The discharged woman was included as not having an invasive procedure. It was considered a plausible clinical assumption that a woman would not have the need for an invasive procedure in the remaining part of the 24-hour time window if she was discharged from the hospital.

9.9.4.1.3 Robustness check

To evaluate the robustness of the study findings, a sensitivity analysis was performed of the primary outcome measure by including the PS (used for selection of matched controls) as an extra covariate in the exact conditional logistic regression model estimating the odds ratio between exposed women and matched controls. In case of problems with convergence of the exact conditional logistic regression the analysis might be replaced with a normal conditional logistic regression.

9.9.4.1.4 Supplementary analysis 1 (exposed controls)

A supplementary analysis was to be conducted if >3 women, selected as matched controls in the PS analysis set, were exposed to NovoSeven® after time0. In this supplementary analysis, exposed controls were excluded, and the exact conditional logistic regression (Section [9.9.4.1.2](#)) was repeated.

The new analysis set created after the above-mentioned exclusion was referred to as supplementary PS analysis set. The excluded matched controls were not replaced, and the balance was not re-assessed.

9.9.4.1.5 Supplementary analysis 2 (additional exposure in both groups)

In supplementary analysis 2, women who were selected as matched controls and later exposed to NovoSeven®, were imputed to have had an invasive procedure after time0. Exposed women with additional doses were also imputed to have had an invasive procedure after time0. For both groups, this only applied if the additional exposure occurred within 24 hours of time0.

The exact conditional logistic regression (Section [9.9.4.1.2](#)) was repeated.

9.9.4.1.6 Supplementary analysis 3 (lag time)

In supplementary analysis 3, to evaluate the effect of the 20-minute lag time in the primary endpoint, alternative lag times were analysed. These “sensitivity endpoints” were made for the following lag times:

- 10 minutes to 24 hours following time0.
- 30 minutes to 24 hours following time0.

The exact conditional logistic regression (Section [9.9.4.1.2](#)) was repeated for these endpoints for the PS analysis set. For these analyses, women with hysterectomy in the window from time0 to time0 +10 minutes and time0 +30 minutes, respectively, were excluded.

9.9.4.1.7 Subgroup analyses

Analyses of the association between exposure to NovoSeven® and the occurrence of invasive procedures during 20 minutes to 24 hours following time0 were repeated for the following subgroups:

- Women having invasive procedures (i.e., uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures or hysterectomy) before matching.
- Women not having invasive procedures before matching.
- Women with vaginal delivery.
- Women with caesarean section.

The above subgroup analyses used the same methods as for the primary analysis. If more than 5 clusters (families of exposed women and their matched control(s)) were dropped from a subgroup then the analysis shifted to a model without condition on the cluster and instead only adjusted for the PS. In Section [10](#) of this report, results are only presented for those subgroups with at least 5 family clusters. The best possible estimates for subgroups with fewer than 5 family clusters can be found in the end-of-text tables in Section [14](#) but should be interpreted with caution.

9.9.4.2 Secondary endpoint analyses

9.9.4.2.1 Occurrence of thromboembolic events

The first secondary objective was to compare frequency of TEs in women with severe PPH treated with NovoSeven® versus matched controls. The comparison was done for the PS analysis set.

The frequency of TEs occurring in the period from time0 until 5 days after time0 was calculated using the PS analysis set as the population at risk (the denominator). Occurrence N (%) of TEs (yes/no) was summarised and compared using risk ratio and 95% CI with two-sided p-value was reported based on Fisher's exact test. The descriptive summary and statistical analysis were also reported separately for ATEs and VTEs.

9.9.4.2.2 Control of bleeding

Two secondary endpoints related to control of bleeding in women with severe PPH treated with NovoSeven® versus women with severe PPH not treated with NovoSeven® were planned:

- Amount of blood products transfused (separately for RBC and FFP).
- Estimated blood loss (mL).

However, the planned analysis of estimated blood loss was not done due to insufficient number of timepoints with an assessment of blood loss.

The amount of blood products transfused was reported as the ratio and/or mean difference between the exposed group and the matched control group of the relative difference pre versus post time0 between the two groups of women. In addition, a comparison of the post time0 levels was made. The analyses were to be done using the PS analysis set.

The total number of blood products (RBC, FFP) units was separately analysed using a negative binomial regression with treatment, period (pre/post time0), the interaction between treatment and period as factors. Patient and matched groups (defined as an exposed woman and her matched controls) were included as a random effect, and (log)duration of each period was included as an offset. The interaction term gave a statistical test for difference in the relative change in blood product use pre and post time0 between the two groups. Ratio of the relative reduction was presented with 95% CI and two-sided p-value. A similar analysis was performed with only post time0 count as outcome and the pre-count divided by the duration of the pre-period as covariates. In a supportive analysis, the amount of blood products between onset of PPH and 24 hours after time0 was investigated by the same approach.

9.9.4.2.3 Hysterectomy

The fourth secondary objective was to compare the incidence of hysterectomy in women with severe PPH exposed to NovoSeven® to the incidence of hysterectomy in women with severe PPH not exposed to NovoSeven®. The comparison of the incidences was analysed using an exact conditional logistic regression model (Section [9.9.4.1.2](#)) for the PS analysis set. The handling of the intercurrent events (death and exposure to NovoSeven® after time0) used the same approach as for the primary analysis. Women with a hysterectomy in the conjoint period were excluded.

9.9.4.3 Exploratory analyses

Several exploratory subgroup analyses were conducted to characterise the PS analysis set. Baseline characteristics and demographics (Section [9.9.3.1](#)), clinical use of NovoSeven® (Section [9.9.3.2](#)), concomitant medications (Section [9.9.3.3](#)) and clinical outcomes (Section [9.9.3.4](#)) were descriptively presented by the following subgroup categories:

Concomitant use of TXA and/or fibrinogen

- Both TXA and fibrinogen
- Only TXA
- Only fibrinogen
- No TXA and no fibrinogen

The groups were mutually exclusive. Any report of TXA and/or fibrinogen was defined as concomitant use. Three time periods were considered: (i) from 24 hours before time0 up to time0; (ii) from time0 to 24 hours after time0; (iii) from 24 hours before time0 to 24 hours after time0.

For endpoints related to invasive procedures only subgroups defined by the first period were used. For transfusions the first two periods were used. For demographics and other baseline data the third period was used.

Cause of PPH

- Uterine atony
- Uterine rupture
- AIP
- Placental abruption
- Placental retention
- Other
- Missing

Timing of first NovoSeven® dose with respect to first invasive procedure

- Without any invasive procedure (women that do not have any invasive procedure during the study)
- Before first invasive procedure (first dose of NovoSeven® occurred before the first invasive procedure, if the invasive procedure occurred during an operation, then NovoSeven® was administered before that operation started)

- During operation with invasive procedure (the first dose of NovoSeven® and the first invasive procedure occurred during the same operation)
- After first invasive procedure (first dose of NovoSeven® occurred after the first invasive procedure, if the invasive procedure occurred during an operation, then NovoSeven® is administered after that operation ended)
- Missing

Timing of first NovoSeven® dose with respect to onset of severe PPH

- <30 minutes after onset of severe PPH
- ≥30 minutes after onset of severe PPH

First dose of NovoSeven® (µg/kg) for matched women exposed to NovoSeven®

- <60 µg/kg
- 60-90 µg/kg
- >90 µg/kg

Gestational age group

- <28 weeks
- 28-37 weeks
- >37 weeks
- Missing

9.9.5 Amendments to the statistical analysis plan

The following changes were made to the statistical methods described in the SAP ([Annex 1](#), [Appendix 16.1.7](#)):

- The analysis of the secondary endpoint of estimated blood loss from delivery to 24 hours after time0 was not done due to insufficient number of timepoints (before and after time0) with assessment of blood loss.
- Haemorrhagic shock and cardiac arrest should have been summarised for the “before conjoint” period, but due to missing day-time data these summaries were not done.
- The proportion (N, %) of women having an event of haemorrhagic shock was summarised; this additional safety parameter was not described in the protocol or SAP but details of haemorrhagic shock were collected in the data collection sheet ([Annex 2](#), [Appendix 16.1.2](#)).

The following subpopulation of the FAS was defined post hoc:

- The population of patients at risk was defined as women in the FAS who received NovoSeven® without pre-planned hysterectomy, or hysterectomy performed before onset of severe PPH, or insufficient data to be part of the PS matching, or with hysterectomy before or in conjoint period with NovoSeven® administration, or with PPH stop before receiving NovoSeven®.

This subpopulation represents those women in the FAS that, after receiving NovoSeven®, were still relevant for evaluating the primary endpoint of occurrence of invasive procedure after the conjoint period. This population was added post hoc as it was not anticipated that a number of patients would have an order of events that made the evaluation of the primary endpoint not at all

meaningful or with limited meaning after NovoSeven® administration. Women who received NovoSeven® after PPH stop due to restart of a bleed or other reasons were excluded as they might have a different risk profile.

For this population two summaries were added

- Proportion of women with any invasive procedure(s), (N, %), after conjoint period.
- Proportion of women with any invasive procedure(s), (N, %), after conjoint period in patients that did not receive an invasive procedure prior to NovoSeven®.

9.9.6 Missing values

Missing data were incorporated in the analyses as a missing category or via imputation. The imputation method depended on the variable in question and the relevant clinical question. The decision was made for each variable separately and based on the number of missing data points, and distribution of the non-missing values.

Many of the data points only have partial timing provided from the data source. Typically, data points were recorded as an event occurring during a certain operation or procedure. Prior to DBL, general business rules were defined to specify the order and timing within an operation for events that occurred within the same operation. These rules were applied in the same manner for both treated and non-treated women. All imputations were reviewed by a team of medically qualified personnel prior to DBL and cases not covered by the general business rules were imputed on a case-by-case basis for the most likely cause and sequence of events. It is possible that some of these imputations may not reflect what actually happened during the event of PPH in a woman, but in order to utilise all available data in the best way possible these imputations were made, as the most likely scenario of the sequence of events. Only in extraordinary cases, with insufficient information to make imputation that was not purely speculative, could a woman be excluded from the PS matching process. All imputations were documented in the DBL minutes. Before the DBL for PS matching, the primary endpoint was blinded to the medical and statistical team to the extent possible.

Missing information of timing on transfusions (RBC and FFP) was handled by interpolation of transfusions between available information on timing.

Imputed day and time were not used to report baseline characteristics, laboratory parameters, NovoSeven® doses and adverse event summaries.

9.10 Quality control

Please see Section [9.8](#) for measures taken to ensure quality and integrity of the data collected in the present study.

10 Results

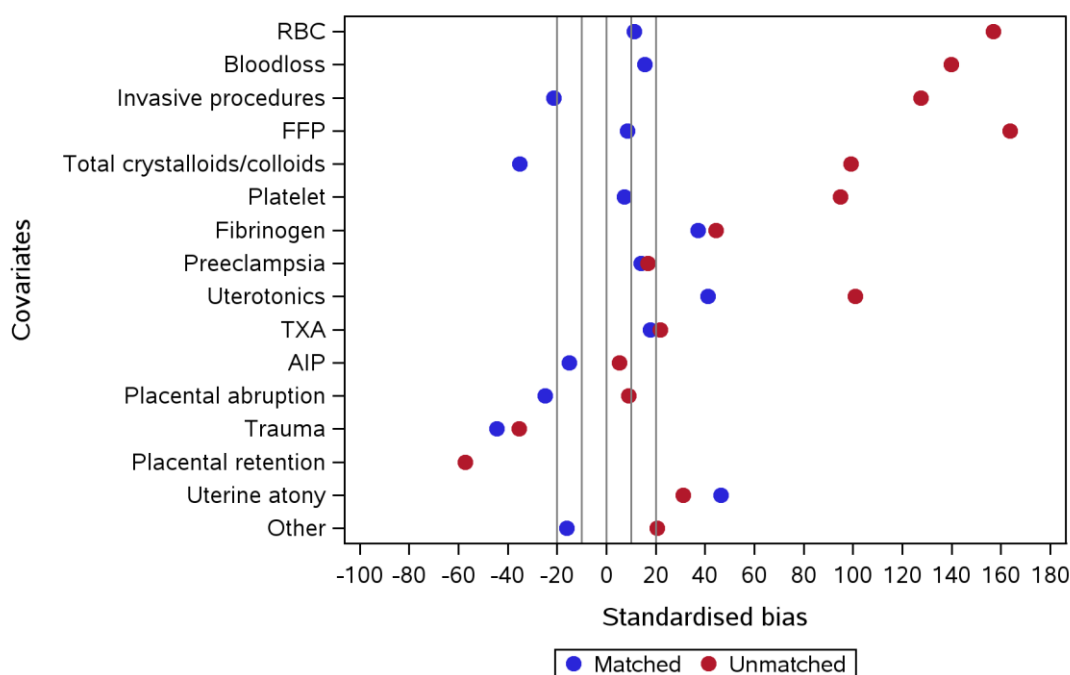
10.1 Participants

10.1.1 Propensity score model selection

The PS model selection process is described in [Annex 2, Appendix 16.2.9.3](#). Matching was done within delivery mode. Five variables were included in the final model: cumulative RBC, cumulative blood loss, number of invasive procedures including balloon, cumulative FFP and total crystalloids/colloids. In addition, for FFP a piecewise linear function was used in which the slope was allowed to change at 0.25 L. There was a high correlation between RBC, FFP and blood loss, but the number of women matched and/or balance was reduced when any of these variables were excluded from the model.

In the standardised bias plot for the final model, the balance after matching was considered to be adequate (within $\pm 20\%$) for the key variables of RBC, blood loss, number of invasive procedures including balloon, and FFP ([Figure 10-1](#)). Total crystalloids/colloids, fibrinogen, uterotonics and cause of PPH were not balanced in the final model (standardised bias not within $\pm 20\%$) but imbalance for these parameters was considered to be acceptable by the study team.

Figure 10-1 Standardised bias plot from propensity score matching – full analysis set



RBC: Red blood cells, FFP: Fresh frozen plasma, TXA: Tranexamic acid, AIP: Abnormally invasive placenta. Values represent ratio of (NovoSeven® mean - Control mean) and pooled standard deviation unmatched.

Notes: Standardised bias is the difference in means between groups divided by the within group standard deviation before matching. Before matching (red dots) and after matching (blue dots). Matched data (blue dots) lying within the bounds for standardised bias of -20 to 20 are considered to be balanced. Invasive procedures include balloon. There were no women with placental retention as cause of severe PPH after matching (no blue dot for this category).

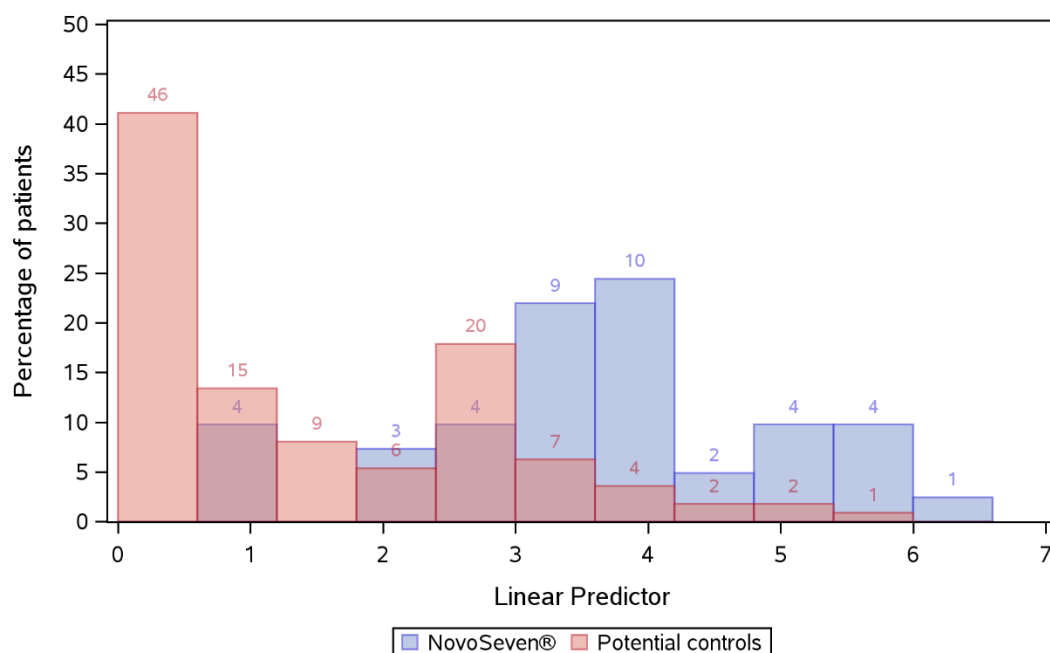
Cross reference: [Annex 2, Appendix 16.2.9.2, Figure 16.2.9.2.1](#)

The distributions of PS (estimated probability of being administered NovoSeven® during the course of PPH) before and after matching are presented in [Figure 10-2](#). It is evident from the top panel that exposed women and potential controls before matching were different and it would be difficult to match all women. After matching, the distribution of PS was well balanced (bottom panel) for matched exposed and control women in the PS analysis set.

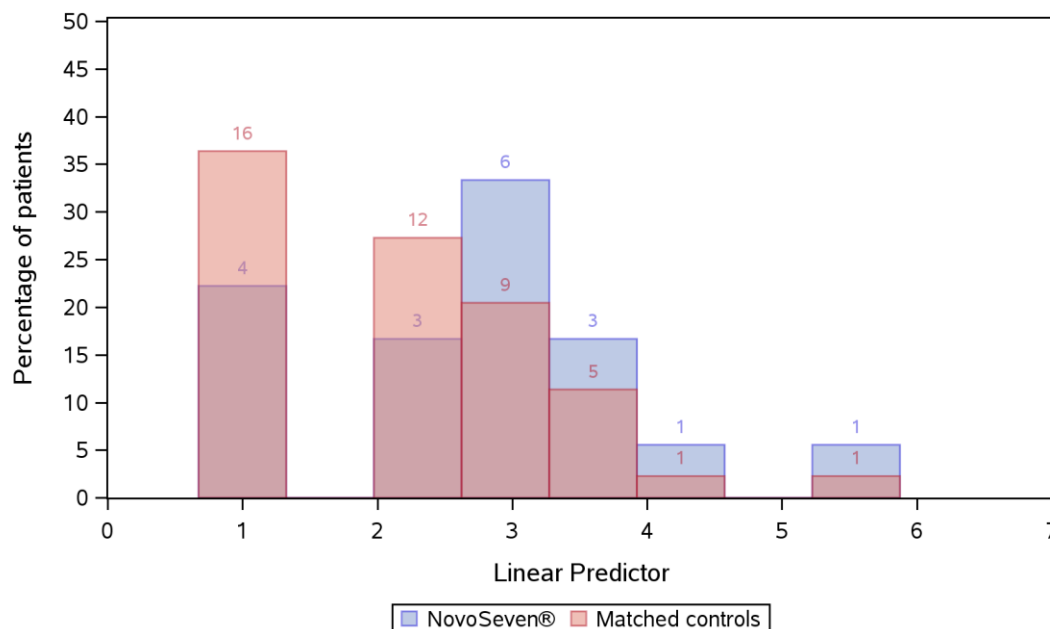
There was a trend that exposed women with low PS for the linear predictor had a higher tendency to be matched than women with a high linear predictor (bottom panel of [Figure 10-2](#)). This means that very severe or very progressed cases were under-represented in the PS analysis set and hence in the final results. Also, there was a tendency that matched exposed women with a lower PS had more controls than matched exposed women with a higher PS. Hence, it is important to compare weighted summary statistics for the matched controls, where they are weighted relative to the size of the matching group.

Figure 10-2 Linear predictor before and after matching – histograms

Before matching (full analysis set)



After matching (PS analysis set)



PS: Propensity score

Cross reference: [Annex 2](#), [Appendix 16.2.9.2](#), [Figures 16.2.9.2.2](#) and [16.2.9.2.3](#)

10.1.2 Patient disposition

10.1.2.1 Full analysis set

A total of 165 women with severe PPH were included in the Bern University Hospital database of which 52 women received NovoSeven® and 113 women did not receive NovoSeven® (Table [14.2.1](#) and [Table 10-1](#)).

A total of 14 women (14 NovoSeven® exposed) were included in cohort 1 (2006 to 2007), 27 women (15 NovoSeven® exposed) were included in cohort 2 (2008 to 2010), 27 women (15 NovoSeven® exposed) were included in cohort 3 (2010 to 2012) and 97 women (8 NovoSeven® exposed) were included in cohort 4 (2013 to 2016) (Table 14.2.42). Please refer to Section 9.2.3 for description of treatment protocols for each of these cohorts.

All 165 women fulfilled the eligibility criteria and were included in the FAS. No woman was excluded from the FAS (Appendix 16.2.3, Listing 16.2.3.1). The women were followed from hospitalisation to discharge.

10.1.2.2 Propensity score analysis set

Before the DBL for PS matching, the primary endpoint was masked to the medical and biostatistical team. Based on the masked data, 153 of the 165 women in the FAS were eligible for PS matching of which 41 were exposed to NovoSeven® (Annex 2, Appendix 16.2.9.3). After DBL for PS matching, 2 women who were originally included as eligible for matching as exposed were no longer eligible for matching and 1 woman became eligible for matching as exposed (Annex 2, Appendix 16.2.9.4), as follows:

- For 2 women, hysterectomy was masked before DBL and they were both included in the matching process as exposed. After DBL and unmasking it was determined that the hysterectomy occurred before NovoSeven® administration. Therefore, these 2 women were not counted as eligible for PS matching in the final output. One of the women had not been matched in the matching process. The other woman had been matched as a control after the hysterectomy; she was removed from the PS analysis set.
- For 1 woman, before DBL the time of hysterectomy was imputed to be before NovoSeven® administration, hence she was not eligible for PS matching. In the final dataset after DBL, the time of hysterectomy was imputed to be after NovoSeven®, therefore she was counted as eligible for matching as exposed in the final output.

Thus, in the final output for PS matching, a total of 153 women were eligible for matching of which 40 women were eligible for matching as exposed (Table 10-1 and Figure 10-3). A total of 12 women overall were not eligible for PS matching due to pre-planned hysterectomy (3 women) or insufficient data (9 women). An additional 12 women were not eligible for PS matching as exposed due to PPH end before receiving NovoSeven® (7 women) or hysterectomy before receiving NovoSeven® (5 women); these 12 women were eligible for PS matching as controls.

After DBL for PS matching, a total of 18 women were included in the PS analysis set as matched exposed and 43 women were included in the PS analysis set as matched controls. A listing of matched exposed women and their controls is presented in Appendix 16.2.6, Listing 16.2.6.1. The women in the PS analysis set were distributed amongst the 4 cohorts (Appendix 16.2.6, Listing 16.2.6.1). Of the 18 matched exposed women, 6, 4, 3 and 5 women were from cohorts 1, 2, 3 and 4, respectively. Of the 43 matched controls, 7, 14, 9 and 13 women were from cohorts 1, 2, 3 and 4, respectively. Characteristics of women excluded from the PS analysis set are presented in Appendix 16.2.3, Listing 16.2.3.2.

In this report, weighted summary statistics are presented for matched controls. The values are weighted according to number of controls selected in the matching process to adjust for difference in number of controls across NovoSeven® exposed women. The 18 clusters for matched controls include a total of 43 individual women.

One of the 43 matched control women in the PS analysis set had a hysterectomy in the conjoint period and was excluded from the primary analysis of ‘occurrence of any invasive procedure in the period from 20 minutes to 24 hours following time0’, since she was no longer at risk of an invasive procedure. Thus, the primary analysis included 18 women as matched exposed and 42 women as matched controls ([Figure 10-3](#)).

Twenty-one of the 43 matched controls were later exposed to NovoSeven® after matching at time0 and 7 of these women were included in the matched exposed group (i.e., included in both the matched control and matched exposed groups with different time0 for each group) ([Appendix 16.2.6, Listing 16.2.6.1](#)).

In the SAP it was specified that at least 50% of the exposed women eligible for matching should be matched with a control. However, this was not possible and only 18 of 40 (45.0%) women eligible for matching as exposed were matched with control(s). The analyses for the PS analysis set were still conducted, as the best comparative data to present, but should be interpreted with caution.

Table 10-1 Patient disposition – full analysis set

	PS analysis set		Full analysis set		
	NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total
Number of patients			52	113	165
Full analysis set with documented sPPH, N (%)			52 (100.0)	113 (100.0)	165 (100.0)
Number of patients with preplanned hysterectomy, N (%)			0	3 (2.7)	3 (1.8)
Number of patients with hysterectomy before sPPH, N (%)			0	0	0
Number of patients not eligible for matching due to insufficient data, N (%)			0	9 (8.0)	9 (5.5)
Number of patients eligible for matching, N (%)			52 (100.0)	101 (89.4)	153 (92.7)
Number of patients with hysterectomy before NovoSeven®, N (%)			5 (9.6)		
Number of patients with PPH stop before NovoSeven® administration, N (%)			7 (13.5)		
Number of patients eligible for matching as exposed, N (%)			40 (76.9)		
Number of patients that were included in matching process as exposed, N (%)			41 (78.8)		
Number of patients eligible for matching as controls, N (%)			51 (98.1)	101 (89.4)	152 (92.1)
Number of patients included in the PS analysis set, N (%)	18 (100.0)	43			
Number of weighted patients, N (%)		18.0 (100.0)			

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients, DBL: Database lock. Categories derived based on imputed dates.

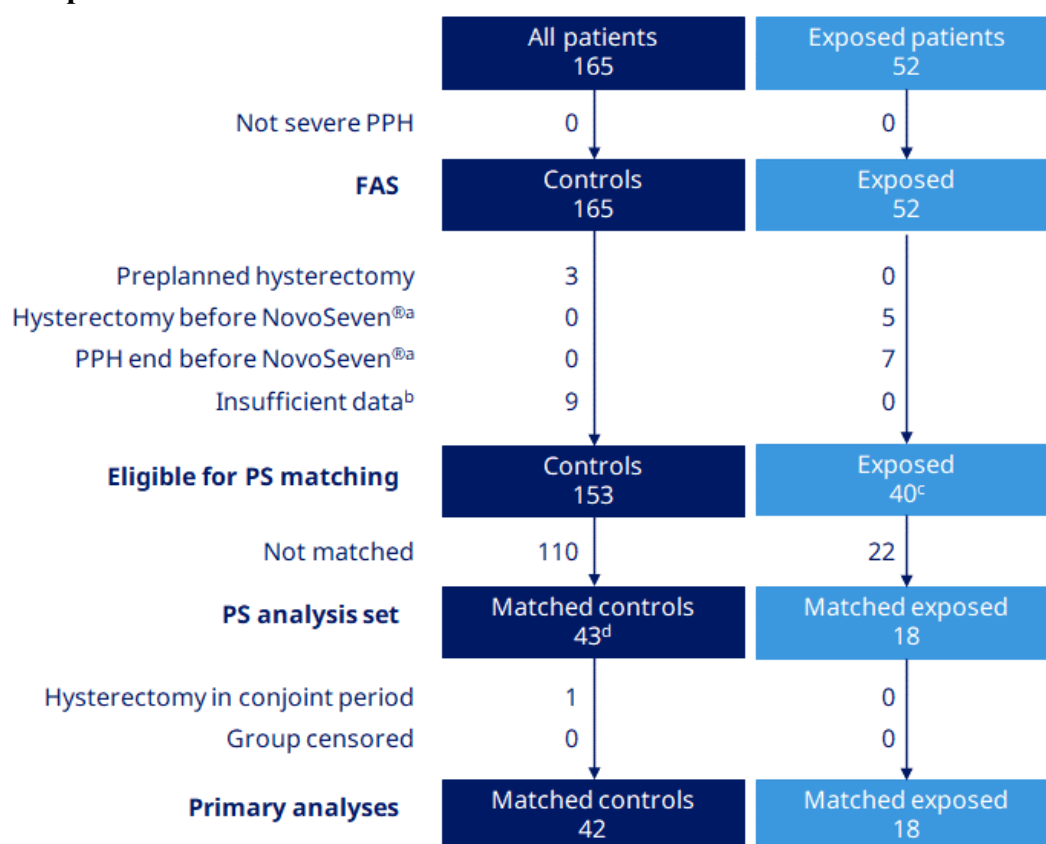
For one patient hysterectomy was masked before the PS matching, hence the patient was included in the matching process as exposed. Then patient was not matched.

For one patient data updates regarding time of hysterectomy changed the patient from not eligible for matching as exposed to eligible. This change was made after the PS DBL.

For another patient hysterectomy was masked before the PS matching, hence the patient was included in the matching process as exposed. Then patient was matched as control after the hysterectomy. The patient was then removed from the PS analysis set.

Cross reference: modified from Table 14.2.1

Figure 10-3 Flow of patients for propensity score matching and primary analyses – all patients



^aNot eligible for matching as exposed women but eligible for matching as controls. ^bSome women had insufficient data on the time course of events to make a meaningful contribution to the PS matching. ^cPS matching was done before unmasked data were available; 2 patients were originally included as eligible that after PS database lock were not eligible for matching as exposed; 1 patient became eligible for matching as exposed. ^dOne patient was matched as control at the same time as PPH ended. One woman was matched as control after hysterectomy and was removed from the PS analysis set accordingly.

Abbreviations: FAS = full analysis set; PPH = postpartum haemorrhage; PS = propensity score

Cross reference: based on Tables 14.2.1 and 14.2.18 and Appendix 16.2.3, Listing 16.2.3.1

10.2 Descriptive data

10.2.1 Patient characteristics

The patient characteristics for the PS analysis set and FAS are presented in full in Table 14.1.1 and summarised below in Table 10-2.

Full analysis set

In the FAS, the NovoSeven® group and the no NovoSeven® group were broadly similar in terms of age distribution (approximately 60% of women aged between 26 to 35 years in both groups), gestational age at delivery (median 38 weeks overall), maternal body weight (median 70 kg overall), number of babies (86.1% of singleton births overall) and gravidity count (median of 2 pregnancies overall) (Table 10-2 and Table 14.1.1).

There were some imbalances in the FAS in the proportions of women with delivery by caesarean section (76.9% vs 50.4% for NovoSeven® and no NovoSeven®, respectively) and obesity (30.8% vs 24.8% for NovoSeven® and no NovoSeven®, respectively). There were also imbalances in the proportions of women with preeclampsia/eclampsia/HELLP (13.5% vs 4.4% for NovoSeven® and no NovoSeven®, respectively) and pre-existing coagulation disorder (3.8% vs 1.8% for NovoSeven® and no NovoSeven®, respectively), although numbers of women with these conditions were small in each group. Median parity count was also numerically lower for the NovoSeven® group (median of 1 birth [IQR 1-2]) than the no NovoSeven® group (median of 2 births [IQR 1-3]).

In the FAS, most women in both groups had a single cause of PPH (71.2% vs 77.0% for NovoSeven® and no NovoSeven®, respectively). There were imbalances in the primary cause of PPH for uterine atony (65.4% vs 42.5% for NovoSeven® and no NovoSeven®, respectively), placental retention (1.9% vs 27.4% for NovoSeven® and no NovoSeven®, respectively) and trauma (1.9% vs 8.0% for NovoSeven® and no NovoSeven®, respectively). Similar proportions of women in both groups had AIP as the primary cause of PPH (17.3% vs 15.0% for NovoSeven® and no NovoSeven®, respectively).

PS analysis set

For the PS analysis set, women were matched based on delivery type, therefore, the percentage of women with delivery by caesarean section and vaginal delivery was identical between NovoSeven® and matched controls (caesarean section was 88.9% for both groups). The two groups of women were broadly similar with regard to other patient characteristics except there were some imbalances in the proportions of women with obesity (33.3% vs 19.0% for NovoSeven® and matched controls, respectively), singleton birth (72.2% vs 91.2% for NovoSeven® and matched controls, respectively), preeclampsia/eclampsia/HELLP (11.1% vs 4.2% for NovoSeven® and matched controls, respectively) and pre-existing coagulation disorder (11.1% vs 0% for NovoSeven® and matched controls, respectively) ([Table 10-2](#) and [Table 14.1.1](#)).

Regarding primary cause of PPH, there were some imbalances in the PS analysis set in the proportions of women with uterine atony (72.2% vs 46.8% for NovoSeven® and matched controls, respectively). Proportions of women with AIP were similar for NovoSeven® and matched controls (22.2% vs 27.8%, respectively). The numbers of women with trauma or other causes of PPH were small in both groups. No woman in the PS analysis set had placental retention as primary cause of PPH.

Patient characteristics for the PS analysis set are presented for subgroups in [Tables 14.1.2 to 14.1.10](#).

Table 10-2 Patient characteristics – PS analysis set and full analysis set

	PS matched analysis set		Full analysis set		
	NovoSeven®	Controls	NovoSeven®	No NovoSeven®	Total
1.0 Number of patients	18	43	52	113	165
Number of weighted patients, N		18.0			
Age at delivery (years), N (%)					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
<=20*	0	0.3 (1.9)	1 (1.9)	3 (2.7)	4 (2.4)
21-25	3 (16.7)	1.9 (10.6)	7 (13.5)	5 (4.4)	12 (7.3)
26-30	7 (38.9)	3.1 (17.1)	15 (28.8)	21 (18.6)	36 (21.8)
31-35	6 (33.3)	4.3 (23.6)	16 (30.8)	46 (40.7)	62 (37.6)
36-40	2 (11.1)	7.1 (39.4)	8 (15.4)	30 (26.5)	38 (23.0)
>40	0	1.3 (7.4)	5 (9.6)	8 (7.1)	13 (7.9)
Gestational age at delivery, (weeks)					
N	18	18.0	52	112	164
Mean (SD)	34.0 (4.9)	36.3 (2.6)	35.5 (4.6)	37.2 (3.9)	36.5 (4.3)
Median (IQR)	34.0 (31.0 - 38.0)	38.0 (33.0 - 40.0)	37.0 (31.0 - 40.0)	38.5 (35.0 - 40.0)	38.0 (34.0 - 40.0)
Min ; Max	23 ; 41	26 ; 42	23 ; 41	23 ; 42	23 ; 42
Maternal body weight, (kg)					
N	18	18.0	52	108	160
Mean (SD)	75.7 (16.8)	72.6 (9.5)	73.8 (17.0)	75.1 (12.5)	74.6 (14.4)
Median (IQR)	70.0 (63.0 - 89.5)	70.0 (63.1 - 80.0)	70.0 (61.0 - 83.0)	72.5 (67.0 - 82.0)	70.0 (64.0 - 82.0)
Min ; Max	52 ; 120	51 ; 115	51 ; 130	48 ; 116	48 ; 130
Delivery type, N (%)					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
Spontaneous vaginal	1 (5.6)	1.0 (5.6)	7 (13.5)	42 (37.2)	49 (29.7)
Instrumental vaginal	1 (5.6)	1.0 (5.6)	5 (9.6)	14 (12.4)	19 (11.5)
I° CS	3 (16.7)	4.3 (23.6)	9 (17.3)	26 (23.0)	35 (21.2)
II° CS	9 (50.0)	6.3 (35.2)	19 (36.5)	18 (15.9)	37 (22.4)
Emergency CS	4 (22.2)	5.4 (30.1)	12 (23.1)	13 (11.5)	25 (15.2)

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		PS matched analysis set		Full analysis set		
		NovoSeven®	Controls	NovoSeven®	No NovoSeven®	Total
1.0	Cause of PPH, N (%)					
	N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
	AIP	4 (22.2)	5.0 (27.8)	9 (17.3)	17 (15.0)	26 (15.8)
	Placental abruption	1 (5.6)	2.3 (12.5)	5 (9.6)	8 (7.1)	13 (7.9)
	Placental retention	0	0	1 (1.9)	31 (27.4)	32 (19.4)
	Uterine atony	13 (72.2)	8.4 (46.8)	34 (65.4)	48 (42.5)	82 (49.7)
	Trauma	0	1.3 (7.4)	1 (1.9)	9 (8.0)	10 (6.1)
	Other	0	1.0 (5.6)	2 (3.8)	0	2 (1.2)
	Single cause	12 (66.7)	12.7 (70.4)	37 (71.2)	87 (77.0)	124 (75.2)
	Multiple cause	6 (33.3)	5.3 (29.6)	15 (28.8)	26 (23.0)	41 (24.8)
	Number of babies					
	N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
	Singleton	13 (72.2)	16.4 (91.2)	44 (84.6)	98 (86.7)	142 (86.1)
	Twins	5 (27.8)	1.3 (7.4)	8 (15.4)	14 (12.4)	22 (13.3)
	> 2 babies	0	0.3 (1.4)	0	1 (0.9)	1 (0.6)
	Parity (count)					
	N	18	18.0	52	113	165
	Mean (SD)	1.4 (0.9)	1.7 (0.6)	1.6 (1.1)	2.1 (1.2)	1.9 (1.2)
	Median (IQR)	1.0(1.0 - 2.0)	2.0(1.0 - 2.0)	1.0(1.0 - 2.0)	2.0(1.0 - 3.0)	2.0(1.0 - 2.0)
	Min ; Max	0 ; 4	1 ; 6	0 ; 7	1 ; 6	0 ; 7
	Gravidity (count)					
	N	18	18.0	52	113	165
	Mean (SD)	1.6 (0.7)	1.9 (0.7)	1.9 (1.5)	1.9 (1.2)	1.9 (1.3)
	Median (IQR)	1.0(1.0 - 2.0)	2.0(1.0 - 2.0)	2.0(1.0 - 2.0)	1.0(1.0 - 2.0)	2.0(1.0 - 2.0)
	Min ; Max	1 ; 3	1 ; 7	1 ; 12	1 ; 7	1 ; 12
	Obesity					
	N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
	Yes	6 (33.3)	3.4 (19.0)	16 (30.8)	28 (24.8)	44 (26.7)
	Pre-existing coagulation disorder					
	N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
	Yes	2 (11.1)	0	2 (3.8)	2 (1.8)	4 (2.4)

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PS matched analysis set			Full analysis set		
	NovoSeven®	Controls	NovoSeven®	No NovoSeven®	Total
Preeclampsia/eclampsia/HELLP, N (%)					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
Yes	2 (11.1)	0.8 (4.2)	7 (13.5)	5 (4.4)	12 (7.3)

*All women were aged >=18 years.

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta, CS: Caesarean section, I° CS: CS before start of delivery, i.e. a planned CS, II° CS: Grade II CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Haemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient has parity as 0 due to sPPH before delivery of the woman's first child.

Cross reference: modified from Table [14.1.1](#)

10.2.2 Concomitant medications

Concomitant medications (e.g. concomitant administration of uterotonics, haemostatic agents and blood products) for the PS analysis set and FAS are presented in Table 14.1.11 by period (from delivery to time0, from time0 until 24 hours after time0, and overall). Concomitant medications and transfusions for the FAS and PS analysis set are summarised for the period from delivery to time0 in Table 10-3. Note that concomitant medications and transfusions for the period from delivery to time0 are not applicable for unexposed women in the FAS because time0 in unexposed women is derived from the matching process.

In the PS analysis set, the NovoSeven® and matched control women were broadly similar regarding the number of doses of oxytocin or other uterotonics administered from delivery to time0. There were some imbalances in the proportions of women who received first dose of TXA from delivery to time0 (55.6% vs 44.4% for NovoSeven® and matched controls, respectively), first dose of fibrinogen from delivery to time0 (33.3% vs 14.4%, respectively) and volume of crystalloids transfused from delivery to time0 (median values of 1733.3 mL vs 2136.7 mL for NovoSeven® and matched controls, respectively). The NovoSeven® and matched control women were also broadly similar regarding the total volumes of RBC (median values of 1100.0 mL in each group), FFP (median values of 980.0 mL vs 1120.0 mL for NovoSeven® and matched controls, respectively), platelets (median values of 125.0 mL for each group) and colloids (median values of 1000.0 mL in each group) transfused from delivery to time0 (Table 10-3).

However, when RBC or FFP before time0 were expressed as rate of transfusions (units per hour), some imbalance was observed between the NovoSeven® exposed women and matched controls, with the rate of transfusions before time0 being numerically higher for NovoSeven® exposed women than matched controls (Table 14.2.45, Figure 14.2.47 and Figure 14.2.48): the estimated mean rates of RBC transfusions before time0 were 1.23 units per hour vs 0.81 units per hour for NovoSeven® exposed and matched controls, respectively, and the estimated mean rates of FFP transfusions before time0 were 1.03 units per hour vs 0.61 units per hour for NovoSeven® exposed and matched controls, respectively.

When comparing the populations of NovoSeven® exposed women in the PS analysis set and FAS, transfusion volumes from delivery to time0 were numerically lower for the PS analysis set than the FAS for RBCs (median 1100.0 mL vs 1650.0 mL), FFP (median 980.0 mL vs 1400.0 mL) and crystalloids (median 1500.0 mL vs 2100.0 mL). These lower transfusion volumes for the matched NovoSeven® exposed women compared with all NovoSeven® exposed women are indicative of the trend for more severe or progressed cases to be under-represented in the PS analysis set because such women could not be matched to a control in the PS model (see Section 10.1.1).

Concomitant medications and transfusions are presented in Tables 14.1.12 to 14.1.22 for subgroups within the PS analysis set.

Table 10-3 Concomitant medications and transfusions from delivery to time0 – PS analysis set and full analysis set

	PS matched analysis set		Full analysis set		
	NovoSeven®	Controls	NovoSeven®	No NovoSeven®	Total
1.0 Number of patients, N	18	43	52	113	165
Number of weighted patients, N		18.0			
Tranexamic acid, N (%)	10 (55.6)	8.0 (44.4)	32 (61.5)		
Fibrinogen, N (%)	6 (33.3)	2.6 (14.4)	14 (26.9)		
Oxytocin (count)					
N	16	15.2	45		
Mean (SD)	2.3 (1.3)	2.2 (0.9)	2.2 (1.3)		
Median (IQR)	2.0 (1.0 – 3.0)	2.0 (1.0 – 3.0)	2.0 (1.0 – 3.0)		
Min ; Max	1 ; 6	1 ; 6	1 ; 6		
Other uterotonics (count)					
N	15	11.9	40		
Mean (SD)	1.7 (0.8)	1.8 (0.7)	1.9 (0.9)		
Median (IQR)	2.0 (1.0 – 2.0)	1.0 (1.0 – 2.0)	2.0 (1.0 – 2.0)		
Min ; Max	1 ; 4	1 ; 4	1 ; 4		
Colloids (mL)					
N	14	16.0	45		
Mean (SD)	1178.6 (668.2)	1169.3 (465.1)	1300.0 (779.0)		
Median (IQR)	1000.0 (500.0 – 1500.0)	1000.0 (500.0 – 1750.0)	1000.0 (500.0 – 2000.0)		
Min ; Max	500 ; 2500	500 ; 2500	500 ; 3500		
Crystalloids (mL)					
N	15	16.9	48		
Mean (SD)	1733.3 (1148.7)	2136.7 (894.7)	2438.5 (1455.9)		
Median (IQR)	1500.0 (1000.0 – 2500.0)	2400.0 (1000.0 – 2700.0)	2100.0 (1225.0 – 3500.0)		
Min ; Max	500 ; 4500	500 ; 7000	500 ; 7000		

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PS matched analysis set			Full analysis set		
	NovoSeven®	Controls	NovoSeven®	No NovoSeven®	Total
Red blood cells (mL)					
N	16	14.3	48		
Mean (SD)	1185.9 (795.2)	1211.0 (467.7)	1907.8 (1133.7)		
Median (IQR)	1100.0 (550.0 - 1650.0)	1100.0 (550.0 - 1650.0)	1650.0 (1100.0 - 2750.0)		
Min ; Max	275 ; 2750	275 ; 2750	275 ; 4675		
FFP transfusion (mL)					
N	14	13.7	45		
Mean (SD)	1220.0 (840.8)	1132.0 (494.2)	1667.6 (895.4)		
Median (IQR)	980.0 (560.0 - 1680.0)	1120.0 (840.0 - 1120.0)	1400.0 (1120.0 - 2240.0)		
Min ; Max	280 ; 2800	280 ; 2800	280 ; 3920		
Platelets (mL)					
N	4.0	3.5	24		
Mean (SD)	125.0 (0.0)	125.0 (0.0)	187.5 (110.6)		
Median (IQR)	125.0 (125.0 - 125.0)	125.0 (125.0 - 125.0)	125.0 (125.0 - 250.0)		
Min ; Max	125 ; 125	125 ; 125	125 ; 500		

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma.
Oxytocin and other uterotonics are summarised based on the number of doses. Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Cross-reference: modified from Table [14.1.11](#)

10.2.3 Clinical outcomes before the conjoint period

Before conjoint period is defined as the period from start of severe PPH to 20 minutes before time0. In the FAS, 32 of 52 (61.5%) women in the NovoSeven® group had any invasive procedure (uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures or hysterectomy) before the conjoint period and 3 (5.8%) women had a hysterectomy before the conjoint period ([Table 10-4](#)). Note that clinical outcomes before the conjoint period are not applicable for unexposed women in the FAS because time0 in unexposed women is derived from the matching process.

In the PS analysis set, a numerically larger proportion of NovoSeven® exposed women than matched controls had any invasive procedure before the conjoint period (61.1% vs 38.9%) and a numerically smaller proportion of NovoSeven® exposed women than matched controls had intrauterine balloon tamponade (0% vs 13.9%) before the conjoint period ([Table 10-4](#)). Women who had a hysterectomy before time0 were excluded from the PS analysis set.

As described previously (Section [10.1.1](#)), the PS model showed acceptable balance for the key covariate of “number of previous invasive procedures including balloon” between exposed and controls after matching ([Figure 10-1](#)). However, this balance was likely achieved by virtue of including balloon as an invasive procedure in the PS model.

Clinical outcomes before the conjoint period for the PS analysis set are presented by subgroups in Tables [14.1.24](#) to [14.1.32](#).

Table 10-4 Clinical outcomes before conjoint period – PS analysis set and full analysis set

	PS matched analysis set		Full analysis set		
	NovoSeven®	Controls	NovoSeven®	No NovoSeven®	Total
1.0 Number of patients	18	43	52	113	165
Number of weighted patients, N		18.0			
Hysterectomy*, N (%)					
Yes	0	0	3 (5.8)		
Other invasive procedure(s)*, N (%)					
Yes	11 (61.1)	7.0 (38.9)	28 (53.8)		
Hysterectomy and other invasive procedure(s)*, N (%)					
Yes	0	0	1 (1.9)		
Any invasive procedure(s), N (%)					
Yes	11 (61.1)	7.0 (38.9)	32 (61.5)		
Laparotomy, N (%)					
Yes	3 (16.7)	3.3 (18.1)	9 (17.3)		
Intrauterine balloon, N (%)					
Yes	0	2.5 (13.9)	6 (11.5)		
Other tamponade, N (%)					
Yes	2 (11.1)	2.3 (13.0)	10 (19.2)		
Removal of placenta, N (%)					
Yes	0	0.5 (2.8)	1 (1.9)		

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients.

Invasive procedures are defined as uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive.

Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

Cross reference: modified from EOT Table [14.1.23](#)

10.2.4 Dose and timing of NovoSeven® administration

10.2.4.1 NovoSeven® dose

The treatment guidelines for each cohort are described in detail in Section 9.2.3. In brief, women in cohort 1 were treated according to an in-house guideline which included NovoSeven® at a suggested dose of 60 µg/kg and women in cohorts 3 and 4 were treated according to a standardised management protocol which included NovoSeven® at suggested doses of 60 µg/kg (cohort 3) or 90 µg/kg (cohort 4), respectively. Additional doses of NovoSeven® could be administered in case of persistent bleeding. No specific treatment guidelines were followed by cohort 2.

In the FAS, 46 (88.5%) women who were treated with NovoSeven® received one dose and 6 (11.5%) women received two doses; no woman received more than two doses (Table 10-5). The median first dose of NovoSeven® in the FAS was 63 µg/kg (IQR 56 to 73 µg/kg), the median second dose was 73 µg/kg (IQR 66 to 85 µg/kg) and the median total dose was 64 µg/kg (IQR 61 to 74 µg/kg). A histogram of first dose of NovoSeven® (µg/kg) is presented in Figure 10-4. Other histograms of NovoSeven® dose for the FAS are presented in Figures 14.2.11 to 14.2.16.

In the PS analysis set, 17 (94.4%) women who were treated with NovoSeven® received one dose and 1 (5.6%) woman received two doses (Table 10-5). Median first and total doses of NovoSeven® were both 65 µg/kg (IQR 62 to 74 µg/kg).

For the 52 women exposed to NovoSeven® in the FAS, the first dose was <60 µg/mL for 14 (26.9%) women, 60-90 µg/mL for 37 (71.2%) women and >90 µg/mL for 1 woman (1.9%) (Table 14.2.90). For the 18 women exposed to NovoSeven® in the PS analysis set, the first dose was <60 µg/mL for 2 (11.1%) women and 60-90 µg/mL for 16 (88.9%) women; no woman in the PS analysis set received a first dose >90 µg/mL (Table 14.1.8).

NovoSeven® doses for the PS analysis set are presented by subgroups in Tables 14.2.4 to 14.2.9.

10.2.4.2 Timing of NovoSeven® administration relative to invasive procedures

In the PS analysis set, most of the women exposed to NovoSeven® received their first dose of NovoSeven® during an invasive procedure (15 of 18 women; 83.3%). No woman received her first dose of NovoSeven® before an invasive procedure, 1 (5.6%) woman received her first dose of NovoSeven® after first invasive procedure and 2 (11.1%) women did not have an invasive procedure (Table 14.2.6).

10.2.4.3 Timing of NovoSeven® administration from onset of severe postpartum haemorrhage

The median time from onset of severe PPH to first dose of NovoSeven® was 127.5 minutes (IQR 71.0 to 290.5 minutes) in the FAS and was shorter at 73.0 minutes (IQR 50.0 to 121.0 minutes) in the PS analysis set (Table 10-6). The median interval between first and second doses was 40.0 minutes (IQR 18.0 to 100.0 minutes) for the 6 women who received a second dose in the FAS and was 40.0 minutes for the 1 woman who received a second dose in the PS analysis set.

Timing of NovoSeven® administration from onset of severe PPH for the PS analysis set is presented by subgroups in Tables 14.2.62 to 14.2.67.

Table 10-5 NovoSeven® doses – PS analysis set and full analysis set

	PS analysis set	Full analysis set
	NovoSeven®	NovoSeven®
1.0 Number of patients	18	52
Total number of NovoSeven® doses per patient, N (%)		
N	18 (100.0)	52 (100.0)
1 dose	17 (94.4)	46 (88.5)
2 doses	1 (5.6)	6 (11.5)
1st dose of NovoSeven® (µg/kg)		
N	18	52
Mean (SD)	67.4 (7.7)	62.7 (16.7)
Median (IQR)	65.0 (62.1 – 73.8)	63.4 (56.4 – 72.7)
Min ; Max	55.4 ; 84.7	12.0 ; 121.2
2nd dose of NovoSeven® (µg/kg)		
N	1	6
Mean (SD)	84.7 (NE)	72.1 (14.4)
Median (IQR)	84.7 (84.7 – 84.7)	73.2 (65.8 – 84.7)
Min ; Max	84.7 ; 84.7	48.0 ; 87.7
Total dose of NovoSeven® (µg/kg)		
N	18	52
Mean (SD)	72.1 (25.1)	71.0 (24.1)
Median (IQR)	65.0 (62.1 – 73.8)	64.0 (60.8 – 73.7)
Min ; Max	55.4 ; 169.5	33.9 ; 169.5
Total dose of NovoSeven® (mg)		
N	18	52
Mean (SD)	4.9 (1.6)	4.9 (1.7)
Median (IQR)	4.8 (4.0 – 5.0)	4.8 (3.6 – 5.2)
Min ; Max	3.6 ; 10.0	2.0 ; 10.0

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile – 75th percentile), NE: Not Estimable.

Cross reference: modified from Table [14.2.3](#)

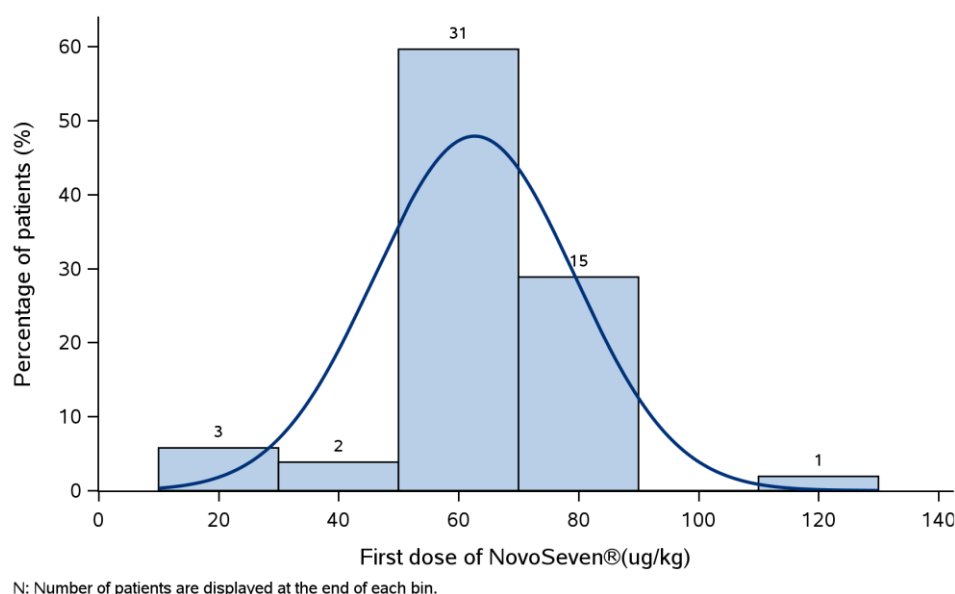
Table 10-6 NovoSeven® administration from onset of severe PPH – PS analysis set and full analysis set

	PS analysis set	Full analysis set
	NovoSeven®	NovoSeven®
Number of patients	18	52
Time from onset of sPPH to first dose of NovoSeven® (minutes)		
N	18	52
Mean (SD)	137.1 (181.6)	228.2 (266.6)
Median (IQR)	73.0 (50.0 - 121.0)	127.5 (71.0 - 290.5)
Min ; Max	3 ; 635	3 ; 1569
Time from first dose to second dose of NovoSeven® (minutes)		
N	1	6
Mean (SD)	40.0 (NE)	216.3 (431.7)
Median (IQR)	40.0 (40.0 - 40.0)	40.0 (18.0 - 100.0)
Min ; Max	40 ; 40	5 ; 1095

PS: Propensity score, sPPH: Severe postpartum haemorrhage, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

Cross reference: modified from Table [14.2.61](#)

Figure 10-4 First dose of NovoSeven® (µg/kg) – histogram – full analysis set



Cross-reference: Figure 14.2.10

10.3 Outcome data

10.3.1 Invasive procedures

Overall clinical outcomes (invasive procedures defined as uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy) are summarised for the PS analysis set and FAS by time of occurrence relative to the conjoint period in [Table 10-7](#). Other types of procedure (laparotomy, intrauterine balloon, other tamponade and removal of placenta) that occurred before, in and after the conjoint period are summarised in [Tables 14.1.23](#), [14.2.68](#) and [14.2.69](#).

In the FAS, 40 of 52 (76.9%) women in the NovoSeven® group had an invasive procedure(s) at any time (before, in or after the conjoint period) compared with 32 of 113 (28.3%) women in the no NovoSeven® group ([Table 10-7](#)). The percentage of women in the FAS with any invasive procedure at any time was higher for women in the NovoSeven® group than for women in the no NovoSeven® group for each individual type of procedure (hysterectomy, radiological arterial embolisation, uterine compression sutures and uterine or iliac artery ligation).

In a post hoc analysis, a total of 13 of 52 women in the NovoSeven® group in the FAS were excluded from the subpopulation of women at risk ([Table 14.2.89](#); see [Section 9.9.5](#) for definition), as the primary endpoint could not be evaluated in these women with a similar interpretation to the remaining women in the FAS. Of the 39 women in the NovoSeven® group who were at risk of further invasive procedure after the conjoint period, 8 (20.5%) women had an invasive procedure after the conjoint period and 31 (79.5%) women did not have an invasive procedure after the conjoint period ([Table 14.2.89](#)). Further, among 12 women in the population at risk without an invasive procedure before NovoSeven®, 2 (16.7%) women had an invasive procedure after the conjoint period and 10 (83.3%) women did not have an invasive procedure after the conjoint period ([Table 14.2.89](#)).

In the PS analysis set, 16 of 18 (88.9%) NovoSeven® exposed women had any invasive procedure(s) at any time (before, in or after conjoint period) compared with 14.1 of 18.0 (78.2%) weighted matched controls ([Table 10-7](#)). The percentage of women in the PS analysis set with any invasive procedure at any time was lower for NovoSeven® exposed women than for matched controls for each individual type of procedure except uterine compression sutures.

An overall summary of patients with invasive procedures is provided in [Table 14.2.2](#). A listing of timing of PPH, NovoSeven®, time0 and invasive procedures is presented in [Appendix 16.2.6, Listing 16.2.6.2](#) and a listing of timing of PPH, NovoSeven®, operation start and stop times is provided in [Appendix 16.2.6, Listing 16.2.6.3](#). A listing of patient information for special cases is provided in [Appendix 16.2.6, Listing 16.2.6.4](#).

By patient plots for the FAS of time from start of severe PPH to invasive procedures for women exposed to NovoSeven® are presented in [Figures 14.2.26 to 14.2.41](#).

Table 10-7 Overall clinical outcomes – invasive procedures – PS analysis set and full analysis set

	PS Analysis set		Full analysis set		
	NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total
Number of patients	18	43	52	113	165
Number of weighted patients, N		18.0			
Invasive procedures at any time, N (%)					
Any invasive procedure(s)	16 (88.9)	14.1 (78.2)	40 (76.9)	32 (28.3)	72 (43.6)
Hysterectomy	2 (11.1)	3.6 (19.9)	11 (21.2)	11 (9.7)	22 (13.3)
Radiological arterial embolisation	1 (5.6)	2.0 (11.1)	7 (13.5)	5 (4.4)	12 (7.3)
Uterine compression sutures	14 (77.8)	10.3 (56.9)	30 (57.7)	20 (17.7)	50 (30.3)
Uterine or iliac artery ligation	1 (5.6)	2.0 (11.1)	4 (7.7)	2 (1.8)	6 (3.6)
No	2 (11.1)	3.9 (21.8)	12 (23.1)	81 (71.7)	93 (56.4)
Missing	0	0	0	3 (2.7)	3 (1.8)
Invasive procedures before conjoint period, N (%)					
Any invasive procedure(s)	11 (61.1)	7.0 (38.9)	32 (61.5)		
Hysterectomy	0	0	3 (5.8)		
Other invasive procedure except hysterectomy	11 (61.1)	7.0 (38.9)	28 (53.8)		
Hysterectomy and other invasive procedure(s)	0	0	1 (1.9)		
Invasive procedures in conjoint period, N (%)					
Any invasive procedure(s)	4 (22.2)	2.8 (15.3)	9 (17.3)		
Hysterectomy	0	0	2 (3.8)		
Other invasive procedure except hysterectomy	4 (22.2)	2.5 (13.9)	7 (13.5)		
Hysterectomy and other invasive procedure(s)	0	0.3 (1.4)	0		
Invasive procedures after conjoint period, N (%)					
Any invasive procedure(s)	3 (16.7)	5.6 (31.0)	11 (21.2)		
Hysterectomy	2 (11.1)	1.8 (10.2)	5 (9.6)		
Other invasive procedure except hysterectomy	1 (5.6)	2.5 (13.9)	6 (11.5)		
Hysterectomy and other invasive procedure(s)	0	1.3 (6.9)	0		

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients. Invasive procedures are defined as uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. The groups hysterectomy, other invasive procedure except hysterectomy, hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 minutes before time0. In conjoint period is defined as 20 minutes before and after time0, After conjoint period is defined as the period from 20 minutes after time0 to 24 hours after time0.

Cross-reference: modified from Tables [14.1.23](#), [14.2.68](#) and [14.2.69](#)

10.3.2 Blood loss

For the FAS, estimated total blood loss throughout the event of severe PPH was numerically higher for women in the NovoSeven® group (median 4500 mL; IQR 4000 to 6000 mL) compared with women in the no NovoSeven® group (median 2000 mL; IQR 1500 to 2800 mL) (Table 14.2.44).

For the PS analysis set, estimated total blood loss throughout the event of severe PPH was similar for NovoSeven® exposed women (median 4550 mL; IQR 3500 to 5500 mL) and matched controls (median 4100 mL; IQR 2900 to 5600 mL) (Table 14.2.44).

10.4 Main results

10.4.1 Primary endpoint

10.4.1.1 Primary analysis

In the PS analysis set, the occurrence of any invasive procedure in the period from 20 minutes to 24 hours following time0 was 16.7% for NovoSeven® exposed women and 31.5% for weighted matched controls. The adjusted odds ratio of any invasive procedure was 0.33 (95% CI: 0.03 to 1.75) in favour of NovoSeven® compared to matched controls; this difference was not statistically significant (p=0.2691) (Table 10-8).

Table 10-8 Primary endpoint – invasive procedures in the period from 20 minutes to 24 hours after time0 – statistical analysis – PS analysis set

	PSAS	N	n	Estimate	95% CI	p-value
Invasive Procedure						
Observed data						
NovoSeven®	18	18	3	16.7		
Matched controls	43	42	13	31.0		
Weighted data						
NovoSeven®	18	18	3	16.7	[-2.4 ; 35.7]	
Matched controls	18.0	17.8	5.6	31.5	[16.8 ; 46.1]	
Adjusted Odds ratio						
NovoSeven®/Matched controls				0.33	[0.03 ; 1.75]	0.2691

PS: Propensity score, PSAS: Propensity score analysis set, N: Number of (weighted) patients used in analysis, n: Number of (weighted) patients having invasive procedure, CI: confidence interval.

Observed data is the raw proportion of events in each group. The weighted data is the proportion with 95% Wald's CI in each group where the matched controls are weighted according to number of controls selected in the matching process to adjust for difference in number of controls across NovoSeven® exposed women. Odds ratio for invasive procedures were compared between NovoSeven® and matched control based on an exact conditional logistic regression model with a 95% exact CI based on the PS matching, along with p-value. Patients with hysterectomy in the conjoint period are excluded from the PSAS (0 patients with NovoSeven® and 1 matched control). Two controls had an invasive procedure after 24 hours window and are not considered in the primary analysis.

Cross-reference: modified from Table 14.2.18

A summary of invasive procedures (weighted data) in the period from 20 minutes to 24 hours following time0 for the PS analysis set is provided in Table 10-9. For the 3 women in the NovoSeven® group who had any invasive procedure in this time frame, 2 had a hysterectomy and

1 had both radiological arterial embolisation and uterine compression suture ([Appendix 16.2.6, Listing 16.2.6.2](#)). For the 13 matched control women (5.6 weighted controls) who had any invasive procedure in this time frame, 8 had a hysterectomy, 3 had radiological arterial embolisation, 4 had uterine compression sutures and 2 had uterine or iliac artery ligation (4 of the 13 matched control women had 2 invasive procedures) ([Appendix 16.2.6, Listing 16.2.6.2](#)).

Table 10-9 Primary endpoint – invasive procedures – summary – PS analysis set

	NovoSeven®	Matched controls
Number of patients	18	43
Number of patients at risk	18	43
Patients having invasive procedure after time0, N (%)		
N	18 (100.0)	18.0 (100.0)
Yes	3 (16.7)	5.6 (31.0)
No	15 (83.3)	12.4 (69.0)
Patients having at least one other invasive procedure before or in conjoint period and receiving another after time0, N (%)		
N	15 (83.3)	9.8 (54.2)
Yes	2 (11.1)	2.3 (12.5)
No	13 (72.2)	7.5 (41.7)
Patients without invasive procedure before or in conjoint period and receiving one after time0, N (%)		
N	3 (16.7)	8.3 (45.8)
Yes	1 (5.6)	3.3 (18.5)
No	2 (11.1)	4.9 (27.3)
Invasive procedure after time0, N (%)		
N	18 (100.0)	18.0 (100.0)
Hysterectomy	2 (11.1)	3.1 (17.1)
Radiological arterial embolisation	1 (5.6)	1.0 (5.6)
Uterine compression sutures	1 (5.6)	2.8 (15.3)
Uterine or iliac artery ligation	0	0.8 (4.2)

N: Number of (weighted) patients, %: Percentage of patients.
Patient at risk: with/without invasive procedures other than hysterectomy before time0.
'Before' means 20 minutes before time0, 'Conjoint' means with in -/+ 20 minutes of time0 and 'after' means 20 minutes to 24 hours after time0.
Two controls had an invasive procedure after 24 hours window are not considered in the primary analysis.

Cross-reference: modified from Table [14.2.17](#)

10.4.1.2 Sensitivity and supplementary analyses

The sensitivity analysis conducted to evaluate the robustness of the primary outcome measure, in which the PS was added as an extra covariate in the exact conditional logistic regression model, supported the findings of the primary analysis. The adjusted odds ratio in this analysis was 0.40 (95% CI: 0.09 to 1.77; p=0.2199) (Table [14.2.21](#)).

Sensitivity analyses conducted to investigate alternative lag times supported the findings of the primary analysis. The adjusted odds ratio was 0.30 (95% CI: 0.03 to 1.55; p=0.2042) for lag time of 10 minutes after time0 (Table [14.2.22](#)) and 0.17 (95% CI: 0.00 to 1.39; p=0.1293) for lag time of 30 minutes after time0 (Table [14.2.23](#)).

Supplementary analyses also supported the findings of the primary analysis. In the analysis in which women selected as matched controls who were later exposed to NovoSeven® were excluded (7 family clusters excluded), the adjusted odds ratio was 0.22^a (95% CI: 0.00 to 1.30; p=0.1667) (Table 14.2.24). In the analysis in which women selected as matched controls and later exposed to NovoSeven® were imputed to have an invasive procedure at the time of the first NovoSeven® exposure and exposed women with additional doses were imputed to have an invasive procedure after time0, the adjusted odds ratio was 0.07 (95% CI: 0.00 to 0.49; p=0.0019) (Table 14.2.25).

10.4.1.3 Subgroup analyses

10.4.1.3.1 By occurrence of invasive procedure(s) before time0

Analyses of the primary endpoint were repeated for subgroups of women with and without invasive procedures before matching at time0 (Table 14.2.19). Family clusters were excluded from the analysis if there was disagreement on invasive procedures before time0 (yes/no) between exposed NovoSeven® cases and their matched controls, e.g. the cluster was excluded if the exposed woman did not have an invasive procedure before time0 but her matched control(s) did have an invasive procedure before time0.

For the 11 clusters of matched women with an invasive procedure before time0, 9.1% of NovoSeven® exposed woman and 20.6% of weighted matched controls had any invasive procedure in the period from 20 minutes to 24 hours following time0 with odds ratio of 0.41 (95% CI: 0.01 to 5.48; p=0.8125) in favour of NovoSeven®.

There were only 2 matched clusters of women without an invasive procedure before time0. Therefore, these results should be interpreted cautiously and are not summarised here (see Table 14.2.19 for the best possible estimate of the odds ratio with the limited data available).

10.4.1.3.2 By mode of delivery

Analyses of the primary endpoint were repeated based on subgroups of women with vaginal or caesarean delivery (Table 14.2.20). Since women were matched based on mode of delivery, no family clusters had to be excluded based on disagreement on mode of delivery between exposed NovoSeven® cases and their matched controls.

For the 16 clusters of matched women with delivery by caesarean section, 12.5% of NovoSeven® exposed woman and 29.1% of weighted matched controls had any invasive procedure in the period from 20 minutes to 24 hours following time0 with odds ratio of 0.23 (95% CI: 0.00 to 1.86); p=0.2628) in favour of NovoSeven®.

There were only 2 matched clusters of women with vaginal delivery. Therefore, these results should be interpreted cautiously and are not summarised here (see Table 14.2.20 for the best possible estimate of the odds ratio with the limited data available).

^a Median unbiased estimate

10.4.1.3.3 Exploratory subgroups

Clinical outcomes during or after the conjoint period for the PS analysis set are presented for exploratory subgroups (concomitant use of TXA and/or fibrinogen, cause of PPH, timing of first dose of NovoSeven® from invasive procedure, first NovoSeven® administration time from onset of severe PPH, first dose of NovoSeven®, and gestational age) in Tables 14.2.70 to 14.2.78, respectively. Due to the small numbers of women in each subgroup or imbalance in the number of women across these subgroups, comparisons between the subgroups are not clinically meaningful.

10.4.2 Secondary endpoints

10.4.2.1 Hysterectomy

In the PS analysis set, 2 (11.1%) NovoSeven® exposed women had a hysterectomy in the period from 20 minutes to 24 hours following time0 compared to 3.1 (17.4%) of weighted matched controls with adjusted odds ratio of 0.52 (95% CI: 0.05 to 3.03) (p=0.6815) in favour of NovoSeven® (Table 10-10).

Table 10-10 Secondary endpoint – incidence of hysterectomy in the period from 20 minutes to 24 hours after time0 – statistical analysis – PS analysis set

	PSAS	N	n	Estimate	95% CI	p-value
Hysterectomy						
Observed data						
NovoSeven®	18	18	2	11.1		
Matched controls	43	42	8	19.0		
Weighted data						
NovoSeven®	18	18	2	11.1	[-5.0 ; 27.2]	
Matched controls	18.0	17.8	3.1	17.4	[5.4 ; 29.3]	
Adjusted Odds ratio						
NovoSeven®/Matched control				0.52	[0.05 ; 3.03]	0.6815

PS: Propensity score, PSAS: Propensity score analysis set, N: Number of (weighted) patients used in analysis, n: Number of (weighted) patients having hysterectomy, CI: confidence interval.

Observed data is the raw proportion of events in each group. The weighted data is the proportion with 95% Wald's CI in each group where the matched controls are weighted according to number of controls selected in the matching process to adjust for difference in number of controls across NovoSeven® exposed women. Odds ratio for invasive procedures were compared between NovoSeven® and matched control based on an exact conditional logistic regression model with a 95% exact CI based on the PS matching, along with p-value. Patients with hysterectomy in the conjoint period are excluded from the PSAS (0 patients with NovoSeven® and 1 matched control).

Cross-reference: Table 14.2.60

10.4.2.2 Amount of blood products transfused

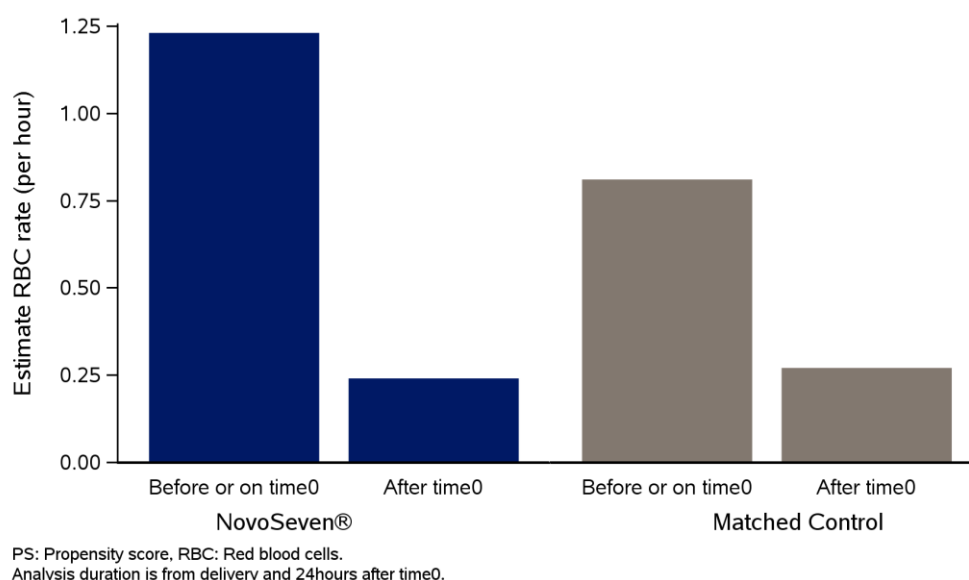
Absolute amounts (units and volume) of blood products transfused in the intervals before or at time0 and up to 24 hours after time0 are summarised for the PS analysis set in Table 14.2.43.

Rates (units per hour) of blood products transfused before or at time0 and after time0 are summarised for the PS analysis set in Table 14.2.45. The mean rates of transfusion (units per hour) for RBC and FFP were lower after time0 than before or at time0 for both NovoSeven® exposed

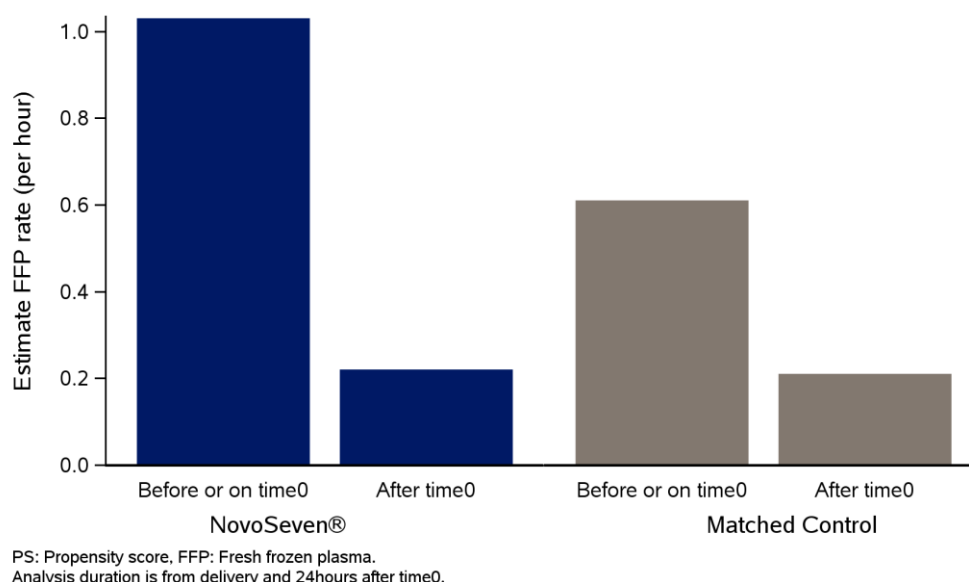
women and matched controls ([Figure 10-5](#) and [Table 10-11](#)). The reductions in rates (after time0/before or at time0) were greater for NovoSeven® exposed women compared to matched controls for RBC (0.19 for NovoSeven® exposed vs 0.33 for matched controls) and FFP (0.21 for NovoSeven® exposed vs 0.35 for matched controls) with a ratio of relative reduction after time0 of 0.58 (95% CI: 0.29 to 1.17; p=0.1253) and 0.61 (95% CI: 0.28 to 1.32; p=0.2044), respectively ([Table 10-11](#)).

Results were similar in a supportive analysis, which investigated amount of blood products between onset of PPH and 24 hours after time0 (Table [14.2.46](#)).

Figure 10-5 Secondary endpoint – blood products transfused – bar plots – PS analysis set
Rate of RBC transfusions



Rate of FFP transfusions



Cross-reference: Figures [14.2.47](#) and [14.2.48](#)

Table 10-11 Secondary endpoint – blood products transfused – statistical analysis – PS analysis set

	PSAS	N	Estimate	SE	95% CI	p-value
RBC transfusions (rate as units per hour)						
NovoSeven®: Before time0	18	18	1.23	0.22	[0.79 ; 1.92]	
NovoSeven®: After time0	18	18	0.24	0.20	[0.16 ; 0.36]	
NovoSeven® reduction: after/before	18	18	0.19	0.29	[0.11 ; 0.34]	
Matched controls: Before time0	43	43	0.81	0.17	[0.58 ; 1.14]	
Matched controls: After time0	43	43	0.27	0.14	[0.20 ; 0.36]	
Matched controls reduction: after/before	43	43	0.33	0.20	[0.22 ; 0.49]	
NovoSeven®/Matched controls ratio of reductions after time0	61	61	0.58	0.35	[0.29 ; 1.17]	0.1253
FFP transfusions (rate as units per hour)						
NovoSeven®: Before time0	18	18	1.03	0.25	[0.63 ; 1.69]	
NovoSeven®: After time0	18	18	0.22	0.22	[0.14 ; 0.35]	
NovoSeven® reduction: after/before	18	18	0.21	0.32	[0.11 ; 0.40]	
Matched controls: Before time0	43	43	0.61	0.19	[0.41 ; 0.89]	
Matched controls: After time0	43	43	0.21	0.16	[0.15 ; 0.29]	
Matched controls reduction: after/before	43	43	0.35	0.22	[0.22 ; 0.55]	
NovoSeven®/Matched controls ratio of reductions after time0	61	61	0.61	0.39	[0.28 ; 1.32]	0.2044

PS: Propensity score, PSAS: Propensity score analysis set, RBC: Red blood cells, FFP: Fresh frozen plasma, N: Number of patients used in analysis, SE: Standard error on log scale, CI: confidence interval.

For transfusions before/ after time0 and relative reductions, a negative binomial regression is performed with treatment, period (before/after time0), the interaction between treatment and period as factors. Patients and matched groups are included as a random effect and (log)duration of each period is included as an offset.

Newton-Raphson technique is used to achieve convergence.

Analysis duration is from delivery to 24 hours after time0.

Cross-reference: modified from Table 14.2.45

10.4.2.3 Estimated blood loss

The analysis of the secondary endpoint of estimated blood loss from delivery to 24 hours after time0 was not done due to insufficient data for the analysis (Table 14.2.49). A summary of estimated blood loss at any time during the event of severe PPH for the PS analysis set is presented in Table 14.2.44 and described in Section 10.3.2.

10.4.2.4 Thromboembolic events

No TEs were reported in the PS analysis set from time0 to within 5 days after time0 for NovoSeven® exposed women or matched controls (Table 14.3.1.4).

See Section 10.6.1 for a summary of TEs in the FAS during the period of hospitalisation.

10.4.3 Summary of main results

- The odds ratio of any invasive procedure from 20 minutes to 24 hours after time0 was 0.33 (95% CI: 0.03 to 1.75) in women with severe PPH treated with NovoSeven® compared to matched controls. This difference was not statistically significant ($p=0.2691$).
- Sensitivity and subgroup analyses for invasive procedures showed consistent and robust results.
- The odds ratio of hysterectomy from 20 minutes to 24 hours after time0 was 0.52 (95% CI: 0.05 to 3.03; $p=0.6815$) in women with severe PPH treated with NovoSeven® compared to matched controls.
- The ratios of relative reduction (after time0/before time0) of RBC and FFP were 0.58 (95% CI: 0.29 to 1.17; $p=0.1253$) and 0.61 (95% CI: 0.28 to 1.32; $p=0.2044$), respectively, in women with severe PPH treated with NovoSeven® compared to matched controls.
- No TEs were reported within the period of 5 days after time0 for women treated with NovoSeven® or matched controls.
- In a post hoc analysis, 39 of the 52 NovoSeven® treated women in the FAS were at risk of further invasive procedure after the conjoint period; of these, 8 (20.5%) women had an invasive procedure after the conjoint period and 31 (79.5%) women did not have an invasive procedure after the conjoint period.

10.5 Other analyses

10.5.1 Hospital information

For the FAS, a numerically larger proportion of women in the NovoSeven® group than the no NovoSeven® group stayed in the ICU or PACU (51.9% vs 23.0%) and median duration of stay was longer for women in the NovoSeven® group than the no NovoSeven® group (12.0 hours vs 9.13 hours) (Table 10-12). Median duration of hospital stay after onset of severe PPH for all women in the FAS (not just those who stayed in ICU or PACU) was also longer for women in the NovoSeven® group than the no NovoSeven® group (8.5 days vs 4.5 days).

For the PS analysis set, 33.3% of NovoSeven® exposed women compared with 50.0% of matched controls stayed in the ICU or PACU and median duration of stay was 12.0 hours for both groups (Table 10-12). Median duration of hospital stay after onset of severe PPH for all women in the PS analysis set was 7.5 days for NovoSeven® exposed women and 8.5 days for matched controls.

Hospital information is presented for exploratory subgroups in Tables [14.2.80](#) to [14.2.88](#).

10.5.2 Duration of bleeding

In the FAS, the duration from onset of severe PPH to stop of severe PPH was numerically longer for the NovoSeven® group (median: 226.0 minutes; IQR: 133.0 to 505.5 minutes) than the no NovoSeven® group (median: 70.0 minutes; IQR: 31.0 to 152.0 minutes) (Table [14.2.50](#)).

In the PS analysis set, the duration from onset of severe PPH to stop of severe PPH was numerically shorter for matched NovoSeven® exposed women (median: 167.5 minutes; IQR: 101.0 to 235.0 minutes) than matched control women (median: 250.0 minutes; IQR: 138.0 to 673.5 minutes) (Table [14.2.50](#)).

Control of bleeding is presented for exploratory subgroups in Tables [14.2.51](#) to [14.2.59](#).

Table 10-12 Hospital information – PS analysis set and full analyses set

	PS analysis set		Full analysis set		
	NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total
Number of patients	18	43	52	113	165
Stay in ICU or PACU, N (%)					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
Yes	6 (33.3)	9.0 (50.0)	27 (51.9)	26 (23.0)	53 (32.1)
No	7 (38.9)	3.6 (19.9)	11 (21.2)	76 (67.3)	87 (52.7)
Missing	5 (27.8)	5.4 (30.1)	14 (26.9)	11 (9.7)	25 (15.2)
Time in ICU or PACU (hours)					
N	6	9.0	27	26	53
Mean (SD)	12.83 (7.39)	11.98 (4.38)	18.32 (21.47)	11.64 (7.43)	15.04 (16.38)
Median (IQR)	12.00 (8.00 – 18.00)	12.00 (6.00 – 16.00)	12.00 (8.00 – 18.50)	9.13 (5.59 – 18.00)	12.00 (6.10 – 18.00)
Min ; Max	3.0 ; 24.0	4.0 ; 24.0	3.0 ; 104.0	2.5 ; 24.0	2.5 ; 104.0
Duration of hospitalisation after onset of sPPH (days)					
N	18	18.0	52	101	153
Mean (SD)	9.09 (3.72)	9.64 (4.75)	9.37 (5.32)	5.62 (6.49)	6.90 (6.36)
Median (IQR)	7.50 (6.40 – 12.00)	8.50 (6.00 – 11.40)	8.50 (6.45 – 11.35)	4.50 (3.40 – 6.50)	5.40 (3.50 – 8.50)
Min ; Max	4.5 ; 16.0	2.0 ; 59.0	2.0 ; 31.9	0.4 ; 59.0	0.4 ; 59.0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, ICU: intensive care unit, PACU: Post anaesthesia care unit.

Cross-reference: Table [14.2.79](#)

10.5.3 Laboratory parameters and body temperature

Laboratory parameters and body temperature at baseline (defined as the closest value to time0 within a time frame of 60 minutes before time0) are summarised for the FAS and PS analysis set in Table 14.3.5.1. Laboratory parameters and body temperature for exploratory subgroups are presented in Tables 14.3.5.2 to 14.3.5.10.

Severe PPH is a rapidly evolving and dynamic situation, therefore, women may have been administered concomitant medication such as fibrinogen or blood products between the time the baseline measurement was taken and the time that NovoSeven® was administered (time0) meaning that the baseline measurement (e.g., of fibrinogen) would no longer be reflective of the woman's clinical condition at time0. For this reason, laboratory parameters at baseline that are affected by supplementation (e.g., fibrinogen supplementation or blood product transfusion) are also summarised in Table 14.3.5.1 for the subset of women who did not receive the corresponding concomitant medication between baseline and time0.

Few women in the PS analysis set had available data for laboratory parameters at baseline, therefore, the descriptions below focus on the FAS for the NovoSeven® group. Note that baseline values are not applicable for unexposed women in the FAS because time0 in unexposed women is derived from the matching process.

Fibrinogen

For the FAS, median fibrinogen level at baseline was 1.66 g/L (IQR: 1.31 to 2.22) for the 22 women in the NovoSeven® group with a baseline measurement and 1.51 g/L (IQR: 1.31 to 2.20) for the subset of 20 women that did not receive fibrinogen supplementation between baseline and time0 (Table 14.3.5.1). The percentage of women with a fibrinogen level ≥ 2 g/L at baseline was 45.5% for the NovoSeven® group overall and 40.0% for the subset of women that did not receive fibrinogen supplementation between baseline and time0.

Haemoglobin

For the FAS, median haemoglobin level at baseline was 82.0 g/L (IQR: 72.0 to 91.0) for the 29 women in the NovoSeven® group with a baseline measurement and 82.0 g/L (IQR: 63.0 to 91.0) for the subset of 9 women that did not receive RBC transfusion between baseline and time0 (Table 14.3.5.1).

Platelets

For the FAS, median platelet level at baseline was 86.0×10^9 /L (IQR: 51.0 to 106.0) for the 25 women in the NovoSeven® group with a baseline measurement and 68.0×10^9 /L (IQR: 43.0 to 112.5) for the subset of 16 women that did not receive platelet supplementation between baseline and time0 (Table 14.3.5.1). The percentage of women with a platelet level $\geq 50 \times 10^9$ /L at baseline was 76.0% for the NovoSeven® group overall and 62.5% for the subset of women that did not receive platelet supplementation between baseline and time0.

pH

For the FAS, median pH level at baseline was 7.31 (IQR: 7.27 to 7.35) for the 18 women in the NovoSeven® group with a baseline measurement and 7.32 (IQR: 7.27 to 7.35) for the subset of

17 women that did not receive crystalloids or colloids between baseline and time0 (Table 14.3.5.1). The percentage of women with a pH ≥ 7.2 at baseline was 94.4% for the NovoSeven® group overall and 94.1% for the subset of women that did not receive crystalloids or colloids between baseline and time0.

Body temperature

For the FAS, median body temperature at baseline was 36.55°C (IQR: 36.20 to 37.00) for the 18 women with a baseline measurement (Table 14.3.5.1). Minimum and maximum recorded body temperatures at baseline were 33.8°C and 38.8°C, respectively.

10.6 Adverse events

The current study was based on data collected retrospectively from medical records of women with severe PPH. Therefore, no individual case safety reporting was performed. Only data captured in the medical records concerning TEs, allergic reactions, cardiac arrest, haemorrhagic shock and maternal death were collected/recorded as adverse events in this report.

This section focuses on adverse events for the FAS during the period of hospitalisation, as summarised in Table 10-13. Adverse events for the PS analysis set during the period of hospitalisation are summarised in Table 14.3.1.2. Analysis of TEs in the PS analysis set within 5 days after time0 is reported as a secondary endpoint in Section 10.4.2.4.

Table 10-13 Summary of adverse events during the period of hospitalisation – full analysis set

	NovoSeven®			No NovoSeven®			Total		
	N	(%)	E	N	(%)	E	N	(%)	E
Number of patients	52			113			165		
Total thromboembolic events	0			1	(0.9)	1	1	(0.6)	1
Arterial thromboembolic event	0			0			0		
Venous thromboembolic event	0			1	(0.9)	1	1	(0.6)	1
Allergic reactions	2	(3.8)	2	0			2	(1.2)	2
Cardiac arrest	1	(1.9)	1	1	(0.9)	1	2	(1.2)	2
Haemorrhagic shock	6	(11.5)	6	4	(3.5)	5	10	(6.1)	11

N: Number of patients with events, %: Percentage of patients with events, E: Number of events.

Number of patients with more than one event are counted once and number of events are counted as per their occurrences. TEs were classified as arterial or venous by medical specialist.

Haemorrhagic shock was only entered in the data collection sheet if it was documented as such in the medical records. Other clinical parameters were not checked to identify if haemorrhagic shock was present.

Cross-reference: modified from Table 14.3.1.1.

10.6.1 Thromboembolic events

In the FAS, none of the women in the NovoSeven® treated group were diagnosed with an ATE or VTE (Table 10-13). A PE was diagnosed █ days after delivery in 1 woman not treated with

NovoSeven® ([Table 10-13](#), [Appendix 16.2.7](#), [Listing 16.2.7.1](#) and ‘data on file’). The PE was verified by computerised tomography scan. This woman had no previous history of TEs and had a normal BMI but had an emergency hysterectomy, thus was at higher thromboembolic risk. She had blood loss of [REDACTED] mL during the event of severe PPH. She received 0.5 g of TXA, 3 doses of oxytocin 20 IU, fraxiparine 0.6 mL, 9 units of RBC, 5 units of FFP, 1.5 L of colloids and 3.2 L of crystalloids; she did not receive fibrinogen or platelets. Note that in the publication by Colucci et al.², it was reported that the PE was diagnosed on day 10 after delivery and that the woman did not receive TXA.

10.6.2 Allergic reactions

In the FAS, an allergic reaction was recorded for 2 women who received NovoSeven® and no women who did not receive NovoSeven® ([Table 10-13](#)). One of the women in the NovoSeven® group with an allergic reaction received two doses of NovoSeven® and the other woman received one dose ([Appendix 16.2.7](#), [Listing 16.2.7.5](#)). The reported terms for the 2 events were “allergic reaction” and “unspecified allergic reaction”, respectively. Both the events of allergic reaction occurred during surgery; in both cases, NovoSeven® dose(s) was administered during the same operation but the order of events is not known.

10.6.3 Cardiac arrest

In the FAS, cardiac arrest was recorded for 1 woman who received NovoSeven® and 1 woman who did not receive NovoSeven® ([Table 10-13](#)). Both women were aged >40 years ([Appendix 16.2.7](#), [Listing 16.2.7.3](#)). For the woman who received NovoSeven®, the cardiac arrest occurred during transfer to Bern University Hospital and before NovoSeven® administration. For the woman who did not receive NovoSeven®, the cardiac arrest occurred during surgery.

10.6.4 Haemorrhagic shock

In the FAS, 6 women treated with NovoSeven® and 4 women not treated with NovoSeven® had a recorded event of haemorrhagic shock ([Table 10-13](#)). One of the 4 women not treated with NovoSeven® had 2 episodes of haemorrhagic shock.

For the 6 women with haemorrhagic shock in the NovoSeven® group, the event occurred before NovoSeven® administration in 2 cases and timing of the event in relation to NovoSeven® administration was not known in the other 4 cases ([Appendix 16.2.7](#), [Listing 16.2.7.4](#)).

The two groups of women (NovoSeven® treated and not treated) with haemorrhagic shock were comparable in terms of age distribution, estimated blood loss (ranging from 3000 mL to 8500 mL) and occurrence of the event during surgery ([Appendix 16.2.7](#), [Listing 16.2.7.4](#)). Most of the women with haemorrhagic shock had uterine atony (5 of 10 women overall) or AIP (4 of 10 women overall) as the primary cause of PPH; 1 woman had trauma as the primary cause of PPH.

Note that haemorrhagic shock was only entered in the data collection sheet if it was documented as such in the medical records. Other clinical parameters were not checked to identify if haemorrhagic shock was present. Therefore, incidence of haemorrhagic shock amongst women in this study might have been higher than reported.

10.6.5 Maternal deaths

No maternal deaths were reported in the study (Table 14.3.1.3 and Appendix 16.2.7, Listing 16.2.7.2).

10.6.6 Special cases

Patient information for special cases is listed in Appendix 16.2.6, Listing 16.2.6.4. Of note:

One woman in the NovoSeven® group had a prolonged hospital stay due to [REDACTED]. The woman was in the age group [REDACTED] years with a BMI of [REDACTED] kg/m². The woman was hospitalised prior to delivery due to pre-eclampsia. Caesarean section was performed pre-term after start of PPH.

One woman in the NovoSeven® group had an emergency caesarean section performed pre-term before the start of PPH due to [REDACTED]. The woman was in the age group [REDACTED] years and had pre-eclampsia.

10.6.7 Summary of adverse events

For the FAS:

- No TEs were reported during the study (from hospitalisation to discharge) in women treated with NovoSeven®.
- The numbers of women with other types of collected adverse events, i.e., cardiac arrest, haemorrhagic shock and allergic reactions, during the period from hospitalisation to discharge were low in both groups (women treated or not treated with NovoSeven®).
- There were no maternal deaths.

11 Discussion

11.1 Key results and interpretation

The PS matching, which included key variables for the likelihood of women with severe PPH receiving NovoSeven®, resulted in approximately 45% of eligible exposed women being matched. A total of 18 women treated with NovoSeven® and 43 matched controls were included in the PS analysis set. The NovoSeven® exposed and matched control groups were broadly balanced in terms of patient characteristics after matching. However, of note, even though the number of prior invasive procedures including balloon were adequately balanced in the final model in terms of standardised bias, a numerically larger proportion of NovoSeven® exposed women than matched controls had invasive procedures excluding balloon prior to the conjoint period (61% vs 39%). Furthermore, although the total volumes of RBC and FFP transfused before time0 were similar between the two groups of women, the rates of transfusion (units per hour) from delivery to time0 were higher for NovoSeven® exposed women than matched controls. These observations suggest that women who were exposed to NovoSeven® may have had more severe or more rapidly developing PPH than matched controls even though the two groups of women were adequately balanced in the PS model.

The primary objective, to compare the occurrence of any invasive procedure after first treatment with NovoSeven® with the occurrence of any invasive procedure without treatment with NovoSeven®, was achieved. The proportion of women with any invasive procedure after the conjoint period was numerically lower for NovoSeven® exposed women than matched controls, but the difference was not statistically significant. Thus, the null hypothesis (that the occurrence of invasive procedures would be similar in the 2 groups) was not able to be rejected. Results for confirmatory and sensitivity analyses confirmed the findings of the primary analysis, with no evidence of any factors adversely affecting the comparison between NovoSeven® and matched controls. Incidence of hysterectomy was compared between groups as a secondary objective; results supported the findings of the primary endpoint with a numerical treatment effect in favour of NovoSeven® compared to matched controls.

Blood transfusions decreased from before time0 to after time0 in both groups. The reductions in rates (after time0/before time0) of transfusion for RBC and FFP were numerically greater for NovoSeven® exposed women compared to matched controls. Due to lack of time varying details in the data for blood loss (few measurements per patient), it was not possible to address the secondary objective to compare blood loss.

No TEs occurred in women exposed to NovoSeven® during hospitalisation and no maternal deaths or additional safety concerns were observed in the reported data. The safety profile of women in the study was consistent with the known NovoSeven® product profile and the population of women with severe PPH.

11.2 Limitations

As this was a non-interventional study, potential confounding factors cannot be ruled out. Additionally, the course of severe PPH is an acute and highly dynamic situation which can be difficult to capture through retrospective data.

Despite matching exposed women and controls based on key clinical variables in the PS model (see Section [10.1.1](#)), there may be factors that were not included in the model because they were not ranked as being of high enough importance (only 5 of the 11 variables identified by experts could be included due to the small number of exposed women eligible for matching). Additionally, it was not possible to include other factors in the model due to insufficient data (e.g. lack of time-dependent information to calculate bleeding rate) or data for a potential variable were not available (e.g. the treating physician's reason for initiating NovoSeven® was not recorded in the medical records). Furthermore, the cause of severe PPH is dynamically evolving during the event but the cause was handled as a static baseline variable in the statistical analysis. Thus, some inherent bias in whether to administer NovoSeven® may still exist in the matched women. In fact, there was some evidence of imbalance in clinical outcomes (e.g., occurrence of invasive procedures and rates of transfusion) before matching, suggesting that women who were treated with NovoSeven® may have been in a worse or more rapidly deteriorating clinical state than their matched controls.

A total of 18 of 40 eligible exposed women could be matched in the PS model and the lack of statistical significance for the primary endpoint could be because of the small number of matched women. The lower than anticipated number of matched women was in part due to the relatively small number of potential controls in the database (approximately 2:1 unexposed to exposed women). Additionally, the distributions of PS for exposed women and potential controls before matching were quite different meaning that it was difficult to match all exposed women. There was a trend that exposed women with a high PS in the linear predictor had a lower tendency to be matched than women with a low PS, meaning that very severe or progressed cases were under-represented in the PS analysis set.

Data were collected as part of routine clinical practice rather than through mandatory assessments at pre-specified time points. This had an impact on the amount of data available and their interpretation. There is lack of detailed insight from the available data about the full clinical and biological profile of the women at the time that NovoSeven® was administered. For example, information on type of bleed (substantial lesion or diffuse), anatomical location of bleed and why NovoSeven® was administered was not available. There was also lack of detailed information on the rate of bleeding, which may have been important in decision making by the treating clinical team. Additionally, there are incomplete data on levels of fibrinogen, platelets and pH at the time of NovoSeven® administration.

Data for the different cohorts were collected at different time periods and were managed according to current practice at the time or standardised management protocols, depending on the cohort, which might have introduced confounders. However, the PS analysis set included exposed women from all 4 cohorts and matched controls came from either the same cohort or from one or several of the other cohorts, binding the data together.

11.3 Generalisability

The inclusion criteria applied in this study were broad and reflected a real-world population of women with severe PPH. All women with severe PPH who were treated at the reporting hospital during the relevant study period for each cohort were included in the hospital database. None of the women in the database were excluded from the FAS for the current study. Bern University Hospital

is a tertiary care centre for the treatment of women with obstetric complications; thus, the population in the current study is representative of women with severe PPH in a developed healthcare setting. The external validity of the study results can be considered high, as the results reflect NovoSeven® use and patient outcomes in real-world clinical practice, albeit from more than 5 years ago.

12 Other information

Not applicable.

13 Conclusion

The FAS included 165 women, including 52 women treated with NovoSeven®. The PS analysis set included 18 women treated with NovoSeven® and 43 matched controls. Most women in the FAS (88.5%) received 1 dose of NovoSeven®, 11.5% received 2 doses and no woman received more than 2 doses. In the FAS, median first dose was 63 µg/kg and median total dose was 64 µg/kg; median time from onset of severe PPH to first dose of NovoSeven® was 127.5 minutes.

- For the small number of women in the PS analysis set, there was a numerical treatment effect in favour of NovoSeven® for the occurrence of any invasive procedure in women treated with NovoSeven® compared to matched controls (odds ratio 0.33; 95% CI: 0.03 to 1.75). The difference was not statistically significant.
- There were also numerical treatment effects in favour of NovoSeven® for occurrence of hysterectomy and relative reduction in rate of blood products transfused in women treated with NovoSeven® compared to matched controls.
- It was not possible to assess the effect of NovoSeven® on blood loss due to insufficient data.
- In a post hoc analysis, 39 of the 52 NovoSeven® treated women in the FAS were at risk of further invasive procedure after the conjoint period; of these, 8 (20.5%) women had an invasive procedure after the conjoint period and 31 (79.5%) women did not have an invasive procedure after the conjoint period.
- There was no indication of increased TE risk with NovoSeven®. No TEs occurred in women treated with NovoSeven®.
- No maternal deaths or additional safety concerns were observed in the reported data.
- The adverse events in this study were consistent with events generally observed in women with severe PPH and with the known safety profile of NovoSeven® in approved indications.

14 Tables, figures and graphs referred to but not included in the text

14.1 Demographic data

14.1.1 Patient characteristics - full analysis set

	PS matched analysis set		Full analysis set		
	NovoSeven®	Controls	NovoSeven®	No NovoSeven®	Total
Number of patients	18	43	52	113	165
Number of weighted patients, N		18.0			
Age at delivery (years), N (%)					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
<=20	0	0.3 (1.9)	1 (1.9)	3 (2.7)	4 (2.4)
21-25	3 (16.7)	1.9 (10.6)	7 (13.5)	5 (4.4)	12 (7.3)
26-30	7 (38.9)	3.1 (17.1)	15 (28.8)	21 (18.6)	36 (21.8)
31-35	6 (33.3)	4.3 (23.6)	16 (30.8)	46 (40.7)	62 (37.6)
36-40	2 (11.1)	7.1 (39.4)	8 (15.4)	30 (26.5)	38 (23.0)
>40	0	1.3 (7.4)	5 (9.6)	8 (7.1)	13 (7.9)
Missing	0	0	0	0	0
Gestational age at delivery, (weeks)					
N	18	18.0	52	112	164
Mean (SD)	34.0 (4.9)	36.3 (2.6)	35.5 (4.6)	37.2 (3.9)	36.5 (4.3)
Median (IQR)	34.0(31.0 - 38.0)	38.0(33.0 - 40.0)	37.0(31.0 - 40.0)	38.5(35.0 - 40.0)	38.0(34.0 - 40.0)
Min ; Max	23 ; 41	26 ; 42	23 ; 41	23 ; 42	23 ; 42
Maternal body weight, (kg)					
N	18	18.0	52	108	160
Mean (SD)	75.7 (16.8)	72.6 (9.5)	73.8 (17.0)	75.1 (12.5)	74.6 (14.4)
Median (IQR)	70.0(63.0 - 89.5)	70.0(63.1 - 80.0)	70.0(61.0 - 83.0)	72.5(67.0 - 82.0)	70.0(64.0 - 82.0)
Min ; Max	52 ; 120	51 ; 115	51 ; 130	48 ; 116	48 ; 130

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: Grade II CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - full analysis set

	PS matched analysis set		Full analysis set		
	NovoSeven®	Controls	NovoSeven®	No NovoSeven®	Total
Delivery type, N (%)					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
Spontaneous vaginal	1 (5.6)	1.0 (5.6)	7 (13.5)	42 (37.2)	49 (29.7)
Instrumental vaginal	1 (5.6)	1.0 (5.6)	5 (9.6)	14 (12.4)	19 (11.5)
I° CS	3 (16.7)	4.3 (23.6)	9 (17.3)	26 (23.0)	35 (21.2)
II° CS	9 (50.0)	6.3 (35.2)	19 (36.5)	18 (15.9)	37 (22.4)
Emergency CS	4 (22.2)	5.4 (30.1)	12 (23.1)	13 (11.5)	25 (15.2)
Missing	0	0	0	0	0
Cause of PPH, N (%)					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
AIP	4 (22.2)	5.0 (27.8)	9 (17.3)	17 (15.0)	26 (15.8)
Placental abruption	1 (5.6)	2.3 (12.5)	5 (9.6)	8 (7.1)	13 (7.9)
Placental retention	0	0	1 (1.9)	31 (27.4)	32 (19.4)
Uterine atony	13 (72.2)	8.4 (46.8)	34 (65.4)	48 (42.5)	82 (49.7)
Trauma	0	1.3 (7.4)	1 (1.9)	9 (8.0)	10 (6.1)
Other	0	1.0 (5.6)	2 (3.8)	0	2 (1.2)
Missing	0	0	0	0	0
Single cause	12 (66.7)	12.7 (70.4)	37 (71.2)	87 (77.0)	124 (75.2)
Multiple cause	6 (33.3)	5.3 (29.6)	15 (28.8)	26 (23.0)	41 (24.8)
Missing	0	0	0	0	0
Number of babies					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
Singleton	13 (72.2)	16.4 (91.2)	44 (84.6)	98 (86.7)	142 (86.1)
Twins	5 (27.8)	1.3 (7.4)	8 (15.4)	14 (12.4)	22 (13.3)
> 2 babies	0	0.3 (1.4)	0	1 (0.9)	1 (0.6)
Missing	0	0	0	0	0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: Grade II CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI $\geq$ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - full analysis set

	PS matched analysis set		Full analysis set		
	NovoSeven®	Controls	NovoSeven®	No NovoSeven®	Total
Parity (count)					
N	18	18.0	52	113	165
Mean (SD)	1.4 (0.9)	1.7 (0.6)	1.6 (1.1)	2.1 (1.2)	1.9 (1.2)
Median (IQR)	1.0 (1.0 - 2.0)	2.0 (1.0 - 2.0)	1.0 (1.0 - 2.0)	2.0 (1.0 - 3.0)	2.0 (1.0 - 2.0)
Min ; Max	0 ; 4	1 ; 6	0 ; 7	1 ; 6	0 ; 7
Parity, N (%)					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
0	1 (5.6)	0	1 (1.9)	0	1 (0.6)
1	10 (55.6)	8.1 (44.9)	29 (55.8)	41 (36.3)	70 (42.4)
2	6 (33.3)	7.9 (44.0)	17 (32.7)	35 (31.0)	52 (31.5)
3	0	1.5 (8.3)	2 (3.8)	27 (23.9)	29 (17.6)
4	1 (5.6)	0	1 (1.9)	4 (3.5)	5 (3.0)
5	0	0.3 (1.4)	1 (1.9)	2 (1.8)	3 (1.8)
>5	0	0.3 (1.4)	1 (1.9)	4 (3.5)	5 (3.0)
Missing	0	0	0	0	0
Gravidity (count)					
N	18	18.0	52	113	165
Mean (SD)	1.6 (0.7)	1.9 (0.7)	1.9 (1.5)	1.9 (1.2)	1.9 (1.3)
Median (IQR)	1.0 (1.0 - 2.0)	2.0 (1.0 - 2.0)	2.0 (1.0 - 2.0)	1.0 (1.0 - 2.0)	2.0 (1.0 - 2.0)
Min ; Max	1 ; 3	1 ; 7	1 ; 12	1 ; 7	1 ; 12

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: Grade II CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI ≥ 30 . BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - full analysis set

	PS matched analysis set		Full analysis set		
	NovoSeven®	Controls	NovoSeven®	No NovoSeven®	Total
Gravidity, N (%)					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
1	10 (55.6)	7.3 (40.3)	25 (48.1)	58 (51.3)	83 (50.3)
2	6 (33.3)	7.3 (40.3)	16 (30.8)	31 (27.4)	47 (28.5)
3	2 (11.1)	2.5 (13.9)	8 (15.4)	15 (13.3)	23 (13.9)
4	0	0.5 (2.8)	2 (3.8)	4 (3.5)	6 (3.6)
5	0	0	0	1 (0.9)	1 (0.6)
>5	0	0.5 (2.8)	1 (1.9)	4 (3.5)	5 (3.0)
Missing	0	0	0	0	0
Obesity					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
Yes	6 (33.3)	3.4 (19.0)	16 (30.8)	28 (24.8)	44 (26.7)
No	11 (61.1)	13.8 (76.9)	33 (63.5)	68 (60.2)	101 (61.2)
Missing	1 (5.6)	0.8 (4.2)	3 (5.8)	17 (15.0)	20 (12.1)
Pre-existing coagulation disorder					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
Yes	2 (11.1)	0	2 (3.8)	2 (1.8)	4 (2.4)
No	16 (88.9)	18.0 (100.0)	50 (96.2)	111 (98.2)	161 (97.6)
Missing	0	0	0	0	0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: Grade II CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI $\geq$ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - full analysis set

		PS matched analysis set		Full analysis set		
		NovoSeven®	Controls	NovoSeven®	No NovoSeven®	Total
1.0	Preeclampsia/eclampsia/HELLP, N (%)					
	N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
	Yes	2 (11.1)	0.8 (4.2)	7 (13.5)	5 (4.4)	12 (7.3)
	No	16 (88.9)	17.3 (95.8)	45 (86.5)	108 (95.6)	153 (92.7)
	History of previous PPH, N (%)					
	N	17 (100.0)	17.4 (100.0)	49 (100.0)	112 (100.0)	161 (100.0)
	Yes	1 (5.9)	1.0 (5.7)	2 (4.1)	12 (10.7)	14 (8.7)
	No	16 (94.1)	16.4 (94.3)	47 (95.9)	100 (89.3)	147 (91.3)
	History of previous caesarean, N (%)					
	N	17 (100.0)	17.4 (100.0)	51 (100.0)	112 (100.0)	163 (100.0)
	Yes	1 (5.9)	4.8 (27.3)	7 (13.7)	22 (19.6)	29 (17.8)
	No	16 (94.1)	12.7 (72.7)	44 (86.3)	90 (80.4)	134 (82.2)

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: Grade II CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI $\geq$ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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14.1.2 Patient characteristics - by concomitant use for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	7	7	1	3
Age at delivery (years), N (%)				
N	7 (100.0)	7 (100.0)	1 (100.0)	3 (100.0)
<=20	0	0	0	0
21-25	1 (14.3)	1 (14.3)	1 (100.0)	0
26-30	2 (28.6)	3 (42.9)	0	2 (66.7)
31-35	2 (28.6)	3 (42.9)	0	1 (33.3)
36-40	2 (28.6)	0	0	0
>40	0	0	0	0
Missing	0	0	0	0
Gestational age at delivery, (weeks)				
N	7	7	1	3
Mean (SD)	34.6 (5.2)	31.3 (4.5)	38.0 (NE)	37.7 (2.1)
Median (IQR)	35.0(31.0 - 40.0)	31.0(30.0 - 33.0)	38.0(38.0 - 38.0)	37.0(36.0 - 40.0)
Min ; Max	27 ; 41	23 ; 38	38 ; 38	36 ; 40
Maternal body weight, (kg)				
N	7	7	1	3
Mean (SD)	78.7 (21.7)	71.6 (15.7)	70.0 (NE)	80.3 (10.0)
Median (IQR)	70.0(62.0 - 92.0)	69.0(61.0 - 89.5)	70.0(70.0 - 70.0)	81.0(70.0 - 90.0)
Min ; Max	60 ; 120	52 ; 95	70 ; 70	70 ; 90

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=)/after(>) time0.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by concomitant use for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Delivery type, N (%)				
N	7 (100.0)	7 (100.0)	1 (100.0)	3 (100.0)
Spontaneous vaginal	0	1 (14.3)	0	0
Instrumental vaginal	1 (14.3)	0	0	0
I° CS	0	2 (28.6)	0	1 (33.3)
II° CS	5 (71.4)	2 (28.6)	0	2 (66.7)
Emergency CS	1 (14.3)	2 (28.6)	1 (100.0)	0
Missing	0	0	0	0
Cause of PPH, N (%)				
N	7 (100.0)	7 (100.0)	1 (100.0)	3 (100.0)
AIP	2 (28.6)	2 (28.6)	0	0
Placental abruption	1 (14.3)	0	0	0
Placental retention	0	0	0	0
Uterine atony	4 (57.1)	5 (71.4)	1 (100.0)	3 (100.0)
Trauma	0	0	0	0
Other	0	0	0	0
Missing	0	0	0	0
Single cause	4 (57.1)	5 (71.4)	1 (100.0)	2 (66.7)
Multiple cause	3 (42.9)	2 (28.6)	0	1 (33.3)
Missing	0	0	0	0
Number of babies				
N	7 (100.0)	7 (100.0)	1 (100.0)	3 (100.0)
Singleton	4 (57.1)	5 (71.4)	1 (100.0)	3 (100.0)
Twins	3 (42.9)	2 (28.6)	0	0
> 2 babies	0	0	0	0
Missing	0	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI $\geq$ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before ($\leq$)/after ($>$) time0.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by concomitant use for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Parity (count)				
N	7	7	1	3
Mean (SD)	1.7 (1.1)	1.1 (0.7)	1.0 (NE)	1.7 (0.6)
Median (IQR)	1.0(1.0 - 2.0)	1.0(1.0 - 2.0)	1.0(1.0 - 1.0)	2.0(1.0 - 2.0)
Min ; Max	1 ; 4	0 ; 2	1 ; 1	1 ; 2
Parity, N (%)				
N	7 (100.0)	7 (100.0)	1 (100.0)	3 (100.0)
0	0	1 (14.3)	0	0
1	4 (57.1)	4 (57.1)	1 (100.0)	1 (33.3)
2	2 (28.6)	2 (28.6)	0	2 (66.7)
3	0	0	0	0
4	1 (14.3)	0	0	0
5	0	0	0	0
>5	0	0	0	0
Missing	0	0	0	0
Gravidity (count)				
N	7	7	1	3
Mean (SD)	1.6 (0.8)	1.4 (0.5)	1.0 (NE)	2.0 (1.0)
Median (IQR)	1.0(1.0 - 2.0)	1.0(1.0 - 2.0)	1.0(1.0 - 1.0)	2.0(1.0 - 3.0)
Min ; Max	1 ; 3	1 ; 2	1 ; 1	1 ; 3

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI ≥ 30 . BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before ($\leq$)/after ($>$) time0.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by concomitant use for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Gravidity, N (%)				
N	7 (100.0)	7 (100.0)	1 (100.0)	3 (100.0)
1	4 (57.1)	4 (57.1)	1 (100.0)	1 (33.3)
2	2 (28.6)	3 (42.9)	0	1 (33.3)
3	1 (14.3)	0	0	1 (33.3)
4	0	0	0	0
5	0	0	0	0
>5	0	0	0	0
Missing	0	0	0	0
Obesity				
N	7 (100.0)	7 (100.0)	1 (100.0)	3 (100.0)
Yes	2 (28.6)	2 (28.6)	0	2 (66.7)
No	5 (71.4)	4 (57.1)	1 (100.0)	1 (33.3)
Missing	0	1 (14.3)	0	0
Pre-existing coagulation disorder				
N	7 (100.0)	7 (100.0)	1 (100.0)	3 (100.0)
Yes	1 (14.3)	1 (14.3)	0	0
No	6 (85.7)	6 (85.7)	1 (100.0)	3 (100.0)
Missing	0	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI $\geq$ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before ($\leq$)/after ($>$) time0.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by concomitant use for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Preeclampsia/eclampsia/HELLP, N (%)				
N	7 (100.0)	7 (100.0)	1 (100.0)	3 (100.0)
Yes	1 (14.3)	1 (14.3)	0	0
No	6 (85.7)	6 (85.7)	1 (100.0)	3 (100.0)
History of previous PPH, N (%)				
N	7 (100.0)	7 (100.0)	1 (100.0)	2 (100.0)
Yes	0	1 (14.3)	0	0
No	7 (100.0)	6 (85.7)	1 (100.0)	2 (100.0)
History of previous caesarean, N (%)				
N	7 (100.0)	7 (100.0)	1 (100.0)	2 (100.0)
Yes	1 (14.3)	0	0	0
No	6 (85.7)	7 (100.0)	1 (100.0)	2 (100.0)

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI ≥ 30 . BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before ($\leq$)/after ($>$) time0.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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14.1.3 Patient characteristics - by concomitant use for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	16	18	1	8
Number of weighted patients, N	5.2	8.8	1.0	3.1
Age at delivery (years), N (%)				
N	5.2 (100.0)	8.8 (100.0)	1.0 (100.0)	3.1 (100.0)
≤20	0.3 (6.5)	0	0	0
21-25	0.3 (4.8)	0.7 (7.6)	1.0 (100.0)	0
26-30	0.8 (16.1)	1.8 (20.0)	0	0.5 (16.2)
31-35	2.3 (43.5)	1.5 (17.1)	0	0.5 (16.2)
36-40	1.3 (24.2)	4.0 (45.7)	0	1.8 (59.5)
>40	0.3 (4.8)	0.8 (9.5)	0	0.3 (8.1)
Missing	0	0	0	0
Gestational age at delivery, (weeks)				
N	5.2	8.8	1.0	3.1
Mean (SD)	37.2 (2.5)	35.9 (2.6)	38.0 (NE)	35.6 (3.2)
Median (IQR)	39.0 (34.0 - 41.0)	36.0 (33.0 - 40.0)	38.0 (38.0 - 38.0)	40.0 (30.0 - 40.0)
Min ; Max	26 ; 42	30 ; 40	38 ; 38	29 ; 40
Maternal body weight, (kg)				
N	5.2	8.8	1.0	3.1
Mean (SD)	72.4 (5.6)	74.0 (12.6)	70.0 (NE)	69.6 (9.0)
Median (IQR)	70.0 (63.1 - 80.0)	70.0 (63.0 - 80.0)	70.0 (70.0 - 70.0)	64.0 (64.0 - 81.0)
Min ; Max	60 ; 93	51 ; 115	70 ; 70	54 ; 100

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.
Obesity is defined as BMI > 30. BMI is calculated based on the weight recorded in the surgery chart.
Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use if the medications were administered 24 hours before(≤)/after(>) time0.

Patient characteristics - by concomitant use for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Delivery type, N (%)				
N	5.2 (100.0)	8.8 (100.0)	1.0 (100.0)	3.1 (100.0)
Spontaneous vaginal	0.5 (9.7)	0.5 (5.7)	0	0
Instrumental vaginal	0	1.0 (11.4)	0	0
I° CS	1.5 (29.0)	2.0 (22.9)	0	0.8 (24.3)
II° CS	1.6 (30.6)	3.4 (39.0)	0	1.3 (43.2)
Emergency CS	1.6 (30.6)	1.8 (21.0)	1.0 (100.0)	1.0 (32.4)
Missing	0	0	0	0
Cause of PPH, N (%)				
N	5.2 (100.0)	8.8 (100.0)	1.0 (100.0)	3.1 (100.0)
AIP	1.6 (30.6)	2.9 (33.3)	0	0.5 (16.2)
Placental abruption	0.3 (4.8)	2.0 (22.9)	0	0
Placental retention	0	0	0	0
Uterine atony	3.3 (64.5)	1.5 (17.1)	1.0 (100.0)	2.6 (83.8)
Trauma	0	1.3 (15.2)	0	0
Other	0	1.0 (11.4)	0	0
Missing	0	0	0	0
Single cause	3.6 (69.4)	5.5 (62.9)	1.0 (100.0)	2.6 (83.8)
Multiple cause	1.6 (30.6)	3.3 (37.1)	0	0.5 (16.2)
Missing	0	0	0	0
Number of babies				
N	5.2 (100.0)	8.8 (100.0)	1.0 (100.0)	3.1 (100.0)
Singleton	4.3 (83.9)	8.0 (91.4)	1.0 (100.0)	3.1 (100.0)
Twins	0.8 (16.1)	0.5 (5.7)	0	0
> 2 babies	0	0.3 (2.9)	0	0
Missing	0	0	0	0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI > 30. BMI is calculated based on the weight recorded in the surgery chart.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use if the medications were administered 24 hours before(=)/after(>) time0.

Patient characteristics - by concomitant use for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Parity (count)				
N	5.2	8.8	1.0	3.1
Mean (SD)	1.8 (0.4)	1.7 (0.6)	1.0 (NE)	2.0 (0.9)
Median (IQR)	2.0 (1.0 - 2.0)	2.0 (1.0 - 2.0)	1.0 (1.0 - 1.0)	2.0 (1.0 - 2.0)
Min ; Max	1 ; 3	1 ; 5	1 ; 1	1 ; 6
Parity, N (%)				
N	5.2 (100.0)	8.8 (100.0)	1.0 (100.0)	3.1 (100.0)
0	0	0	0	0
1	1.9 (37.1)	3.9 (44.8)	1.0 (100.0)	1.3 (40.5)
2	2.3 (43.5)	4.3 (49.5)	0	1.3 (43.2)
3	1.0 (19.4)	0.3 (2.9)	0	0.3 (8.1)
4	0	0	0	0
5	0	0.3 (2.9)	0	0
>5	0	0	0	0.3 (8.1)
Missing	0	0	0	0
Gravidity (count)				
N	5.2	8.8	1.0	3.1
Mean (SD)	2.0 (0.6)	1.9 (0.7)	1.0 (NE)	2.2 (1.1)
Median (IQR)	2.0 (1.0 - 3.0)	2.0 (1.0 - 2.0)	1.0 (1.0 - 1.0)	2.0 (1.0 - 2.0)
Min ; Max	1 ; 4	1 ; 6	1 ; 1	1 ; 7

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI > 30. BMI is calculated based on the weight recorded in the surgery chart.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use if the medications were administered 24 hours before(=)/after(>) time0.

Patient characteristics - by concomitant use for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Gravidity, N (%)				
N	5.2 (100.0)	8.8 (100.0)	1.0 (100.0)	3.1 (100.0)
1	2.2 (41.9)	2.8 (32.4)	1.0 (100.0)	1.3 (40.5)
2	1.5 (29.0)	4.7 (53.3)	0	1.1 (35.1)
3	1.0 (19.4)	1.0 (11.4)	0	0.5 (16.2)
4	0.5 (9.7)	0	0	0
5	0	0	0	0
>5	0	0.3 (2.9)	0	0.3 (8.1)
Missing	0	0	0	0
Obesity				
N	5.2 (100.0)	8.8 (100.0)	1.0 (100.0)	3.1 (100.0)
Yes	0.8 (16.1)	1.8 (20.0)	0	0.8 (27.0)
No	4.1 (79.0)	6.5 (74.3)	1.0 (100.0)	2.3 (73.0)
Missing	0.3 (4.8)	0.5 (5.7)	0	0
Pre-existing coagulation disorder				
N	5.2 (100.0)	8.8 (100.0)	1.0 (100.0)	3.1 (100.0)
Yes	0	0	0	0
No	5.2 (100.0)	8.8 (100.0)	1.0 (100.0)	3.1 (100.0)
Missing	0	0	0	0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI > 30. BMI is calculated based on the weight recorded in the surgery chart.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use if the medications were administered 24 hours before(=)/after(>) time0.

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Patient characteristics - by concomitant use for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Preeclampsia/eclampsia/HELLP, N (%)				
N	5.2 (100.0)	8.8 (100.0)	1.0 (100.0)	3.1 (100.0)
Yes	0.3 (4.8)	0.3 (2.9)	0	0.3 (8.1)
No	4.9 (95.2)	8.5 (97.1)	1.0 (100.0)	2.8 (91.9)
History of previous PPH, N (%)				
N	5.2 (100.0)	8.8 (100.0)	1.0 (100.0)	2.5 (100.0)
Yes	0.5 (9.7)	0.5 (5.7)	0	0
No	4.7 (90.3)	8.3 (94.3)	1.0 (100.0)	2.5 (100.0)
History of previous caesarean, N (%)				
N	5.2 (100.0)	8.8 (100.0)	1.0 (100.0)	2.5 (100.0)
Yes	1.3 (24.2)	2.5 (28.6)	0	1.0 (40.0)
No	3.9 (75.8)	6.3 (71.4)	1.0 (100.0)	1.5 (60.0)

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI > 30. BMI is calculated based on the weight recorded in the surgery chart.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use if the medications were administered 24 hours before(<=)/after(>) time0.

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14.1.4 Patient characteristics - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention
Number of patients	4	1	0
Age at delivery (years), N (%)			
N	4 (100.0)	1 (100.0)	0
<=20	0	0	
21-25	1 (25.0)	0	
26-30	2 (50.0)	0	
31-35	0	1 (100.0)	
36-40	1 (25.0)	0	
>40	0	0	
Missing	0	0	
Gestational age at delivery, (weeks)			
N	4	1	0
Mean (SD)	35.3 (4.8)	31.0 (NE)	
Median (IQR)	35.0 (31.5 - 39.0)	31.0 (31.0 - 31.0)	
Min ; Max	30 ; 41	31 ; 31	
Maternal body weight, (kg)			
N	4	1	0
Mean (SD)	59.6 (5.7)	92.0 (NE)	
Median (IQR)	61.5 (55.8 - 63.5)	92.0 (92.0 - 92.0)	
Min ; Max	52 ; 64	92 ; 92	

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets. Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart. One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	Uterine atony	Trauma	Other
Number of patients	13	0	0
Age at delivery (years), N (%)			
N	13 (100.0)	0	0
≤20	0		
21-25	2 (15.4)		
26-30	5 (38.5)		
31-35	5 (38.5)		
36-40	1 (7.7)		
>40	0		
Missing	0		
Gestational age at delivery, (weeks)			
N	13	0	0
Mean (SD)	33.8 (5.1)		
Median (IQR)	35.0 (31.0 - 38.0)		
Min ; Max	23 ; 40		
Maternal body weight, (kg)			
N	13	0	0
Mean (SD)	79.4 (16.3)		
Median (IQR)	72.0 (70.0 - 89.5)		
Min ; Max	61 ; 120		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.
Obesity is defined as BMI ≥ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.
One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention
Delivery type, N (%)			
N	4 (100.0)	1 (100.0)	0
Spontaneous vaginal	1 (25.0)	0	
Instrumental vaginal	1 (25.0)	0	
I° CS	0	0	
II° CS	2 (50.0)	0	
Emergency CS	0	1 (100.0)	
Missing	0	0	
Cause of PPH, N (%)			
N	4 (100.0)	1 (100.0)	0
AIP	4 (100.0)	0	
Placental abruption	0	1 (100.0)	
Placental retention	0	0	
Uterine atony	0	0	
Trauma	0	0	
Other	0	0	
Missing	0	0	
Single cause	2 (50.0)	1 (100.0)	
Multiple cause	2 (50.0)	0	
Missing	0	0	
Number of babies			
N	4 (100.0)	1 (100.0)	0
Singleton	4 (100.0)	1 (100.0)	
Twins	0	0	
> 2 babies	0	0	
Missing	0	0	

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLF: Hemolysis, Elevated Liver enzymes and Low Platelets. Obesity is defined as BMI ≥ 30 . BMI (body mass index) is calculated based on the weight recorded in the surgery chart. One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	Uterine atony	Trauma	Other
Delivery type, N (%)			
N	13 (100.0)	0	0
Spontaneous vaginal	0		
Instrumental vaginal	0		
I° CS	3 (23.1)		
II° CS	7 (53.8)		
Emergency CS	3 (23.1)		
Missing	0		
Cause of PPH, N (%)			
N	13 (100.0)	0	0
AIP	0		
Placental abruption	0		
Placental retention	0		
Uterine atony	13 (100.0)		
Trauma	0		
Other	0		
Missing	0		
Single cause	9 (69.2)		
Multiple cause	4 (30.8)		
Missing	0		
Number of babies			
N	13 (100.0)	0	0
Singleton	8 (61.5)		
Twins	5 (38.5)		
> 2 babies	0		
Missing	0		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets. Obesity is defined as BMI ≥ 30 . BMI (body mass index) is calculated based on the weight recorded in the surgery chart. One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention
Parity (count)			
N	4	1	0
Mean (SD)	1.8 (0.5)	4.0 (NE)	
Median (IQR)	2.0 (1.5 - 2.0)	4.0 (4.0 - 4.0)	
Min ; Max	1 ; 2	4 ; 4	
Parity, N (%)			
N	4 (100.0)	1 (100.0)	0
0	0	0	
1	1 (25.0)	0	
2	3 (75.0)	0	
3	0	0	
4	0	1 (100.0)	
5	0	0	
>5	0	0	
Missing	0	0	
Gravidity (count)			
N	4	1	0
Mean (SD)	1.8 (0.5)	2.0 (NE)	
Median (IQR)	2.0 (1.5 - 2.0)	2.0 (2.0 - 2.0)	
Min ; Max	1 ; 2	2 ; 2	

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets. Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart. One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	Uterine atony	Trauma	Other
Parity (count)			
N	13	0	0
Mean (SD)	1.2 (0.6)		
Median (IQR)	1.0 (1.0 - 1.0)		
Min ; Max	0 ; 2		
Parity, N (%)			
N	13 (100.0)	0	0
0	1 (7.7)		
1	9 (69.2)		
2	3 (23.1)		
3	0		
4	0		
5	0		
>5	0		
Missing	0		
Gravidity (count)			
N	13	0	0
Mean (SD)	1.5 (0.8)		
Median (IQR)	1.0 (1.0 - 2.0)		
Min ; Max	1 ; 3		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets. Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart. One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention
Gravidity, N (%)			
N	4 (100.0)	1 (100.0)	0
1	1 (25.0)	0	
2	3 (75.0)	1 (100.0)	
3	0	0	
4	0	0	
5	0	0	
>5	0	0	
Missing	0	0	
Obesity			
N	4 (100.0)	1 (100.0)	0
Yes	0	1 (100.0)	
No	3 (75.0)	0	
Missing	1 (25.0)	0	
Pre-existing coagulation disorder			
N	4 (100.0)	1 (100.0)	0
Yes	0	0	
No	4 (100.0)	1 (100.0)	
Missing	0	0	

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI $\geq$ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	Uterine atony	Trauma	Other
Gravidity, N (%)			
N	13 (100.0)	0	0
1	9 (69.2)		
2	2 (15.4)		
3	2 (15.4)		
4	0		
5	0		
>5	0		
Missing	0		
Obesity			
N	13 (100.0)	0	0
Yes	5 (38.5)		
No	8 (61.5)		
Missing	0		
Pre-existing coagulation disorder			
N	13 (100.0)	0	0
Yes	2 (15.4)		
No	11 (84.6)		
Missing	0		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI $\geq$ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention
Preeclampsia/eclampsia/HELLP, N (%)			
N	4 (100.0)	1 (100.0)	0
Yes	0	1 (100.0)	
No	4 (100.0)	0	
History of previous PPH, N (%)			
N	4 (100.0)	1 (100.0)	0
Yes	1 (25.0)	0	
No	3 (75.0)	1 (100.0)	
History of previous caesarean, N (%)			
N	4 (100.0)	1 (100.0)	0
Yes	0	1 (100.0)	
No	4 (100.0)	0	

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets. Obesity is defined as BMI ≥ 30 . BMI (body mass index) is calculated based on the weight recorded in the surgery chart. One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	Uterine atony	Trauma	Other
Preeclampsia/eclampsia/HELLP, N (%)			
N	13 (100.0)	0	0
Yes	1 (7.7)		
No	12 (92.3)		
History of previous PPH, N (%)			
N	12 (100.0)	0	0
Yes	0		
No	12 (100.0)		
History of previous caesarean, N (%)			
N	12 (100.0)	0	0
Yes	0		
No	12 (100.0)		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets. Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart. One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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14.1.5 Patient characteristics - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention
Number of patients	14	3	0
Number of weighted patients, N	5.0	2.3	0
Age at delivery (years), N (%)			
N	5.0 (100.0)	2.3 (100.0)	0
<=20	0	0	
21-25	0.6 (11.7)	0	
26-30	1.1 (21.7)	0	
31-35	0.5 (10.0)	0.3 (11.1)	
36-40	2.3 (45.0)	2.0 (88.9)	
>40	0.6 (11.7)	0	
Missing	0	0	
Gestational age at delivery, (weeks)			
N	5.0	2.3	0
Mean (SD)	33.3 (2.3)	38.6 (1.7)	
Median (IQR)	33.0 (31.0 - 34.0)	38.0 (38.0 - 40.0)	
Min ; Max	26 ; 42	35 ; 40	
Maternal body weight, (kg)			
N	5.0	2.3	0
Mean (SD)	68.1 (5.7)	95.1 (18.9)	
Median (IQR)	70.0 (63.0 - 71.0)	80.0 (80.0 - 115.0)	
Min ; Max	51 ; 84	76 ; 115	

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

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Patient characteristics - by cause of PPH for matched controls - PS analysis set

	Uterine atony	Trauma	Other
Number of patients	23	2	1
Number of weighted patients, N	8.4	1.3	1.0
Age at delivery (years), N (%)			
N	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
≤20	0.3 (4.0)	0	0
21-25	1.0 (11.9)	0.3 (25.0)	0
26-30	1.0 (11.9)	0	1.0 (100.0)
31-35	2.5 (29.7)	1.0 (75.0)	0
36-40	2.8 (33.7)	0	0
>40	0.8 (8.9)	0	0
Missing	0	0	0
Gestational age at delivery, (weeks)			
N	8.4	1.3	1.0
Mean (SD)	36.9 (2.4)	37.3 (3.5)	40.0 (NE)
Median (IQR)	38.0 (34.0 - 40.0)	39.0 (35.5 - 39.0)	40.0 (40.0 - 40.0)
Min ; Max	29 ; 41	32 ; 39	40 ; 40
Maternal body weight, (kg)			
N	8.4	1.3	1.0
Mean (SD)	71.3 (7.4)	68.5 (3.0)	60.0 (NE)
Median (IQR)	70.0 (63.1 - 75.0)	70.0 (67.0 - 70.0)	60.0 (60.0 - 60.0)
Min ; Max	54 ; 100	64 ; 70	60 ; 60

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI ≥ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

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Patient characteristics - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention
Delivery type, N (%)			
N	5.0 (100.0)	2.3 (100.0)	0
Spontaneous vaginal	1.0 (20.0)	0	
Instrumental vaginal	0	0	
I° CS	2.3 (45.0)	0.3 (11.1)	
II° CS	1.3 (25.0)	1.0 (44.4)	
Emergency CS	0.5 (10.0)	1.0 (44.4)	
Missing	0	0	
Cause of PPH, N (%)			
N	5.0 (100.0)	2.3 (100.0)	0
AIP	5.0 (100.0)	0	
Placental abruption	0	2.3 (100.0)	
Placental retention	0	0	
Uterine atony	0	0	
Trauma	0	0	
Other	0	0	
Missing	0	0	
Single cause	2.2 (43.3)	1.0 (44.4)	
Multiple cause	2.8 (56.7)	1.3 (55.6)	
Missing	0	0	
Number of babies			
N	5.0 (100.0)	2.3 (100.0)	0
Singleton	4.4 (88.3)	2.3 (100.0)	
Twins	0.3 (6.7)	0	
> 2 babies	0.3 (5.0)	0	
Missing	0	0	

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI $\geq$ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

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Patient characteristics - by cause of PPH for matched controls - PS analysis set

	Uterine atony	Trauma	Other
Delivery type, N (%)			
N	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
Spontaneous vaginal	0	0	0
Instrumental vaginal	0	1.0 (75.0)	0
I° CS	1.8 (20.8)	0	0
II° CS	3.1 (36.6)	0	1.0 (100.0)
Emergency CS	3.6 (42.6)	0.3 (25.0)	0
Missing	0	0	0
Cause of PPH, N (%)			
N	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
AIP	0	0	0
Placental abruption	0	0	0
Placental retention	0	0	0
Uterine atony	8.4 (100.0)	0	0
Trauma	0	1.3 (100.0)	0
Other	0	0	1.0 (100.0)
Missing	0	0	0
Single cause	7.2 (85.1)	1.3 (100.0)	1.0 (100.0)
Multiple cause	1.3 (14.9)	0	0
Missing	0	0	0
Number of babies			
N	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
Singleton	7.4 (88.1)	1.3 (100.0)	1.0 (100.0)
Twins	1.0 (11.9)	0	0
> 2 babies	0	0	0
Missing	0	0	0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

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Patient characteristics - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention
Parity (count)			
N	5.0	2.3	0
Mean (SD)	2.2 (0.7)	1.4 (0.5)	
Median (IQR)	2.0 (2.0 - 2.0)	1.0 (1.0 - 2.0)	
Min ; Max	1 ; 6	1 ; 2	
Parity, N (%)			
N	5.0 (100.0)	2.3 (100.0)	0
0	0	0	
1	0.9 (18.3)	1.3 (55.6)	
2	3.1 (61.7)	1.0 (44.4)	
3	0.8 (15.0)	0	
4	0	0	
5	0	0	
>5	0.3 (5.0)	0	
Missing	0	0	
Gravidity (count)			
N	5.0	2.3	0
Mean (SD)	2.2 (0.8)	1.9 (0.3)	
Median (IQR)	2.0 (2.0 - 2.0)	2.0 (2.0 - 2.0)	
Min ; Max	1 ; 7	1 ; 2	

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

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Patient characteristics - by cause of PPH for matched controls - PS analysis set

	Uterine atony	Trauma	Other
Parity (count)			
N	8.4	1.3	1.0
Mean (SD)	1.6 (0.5)	1.0 (0.0)	2.0 (NE)
Median (IQR)	1.0 (1.0 - 2.0)	1.0 (1.0 - 1.0)	2.0 (2.0 - 2.0)
Min ; Max	1 ; 5	1 ; 1	2 ; 2
Parity, N (%)			
N	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
0	0	0	0
1	4.6 (54.5)	1.3 (100.0)	0
2	2.8 (33.7)	0	1.0 (100.0)
3	0.8 (8.9)	0	0
4	0	0	0
5	0.3 (3.0)	0	0
>5	0	0	0
Missing	0	0	0
Gravidity (count)			
N	8.4	1.3	1.0
Mean (SD)	1.8 (0.7)	1.0 (0.0)	3.0 (NE)
Median (IQR)	1.0 (1.0 - 2.0)	1.0 (1.0 - 1.0)	3.0 (3.0 - 3.0)
Min ; Max	1 ; 6	1 ; 1	3 ; 3

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

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Patient characteristics - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention
Gravidity, N (%)			
N	5.0 (100.0)	2.3 (100.0)	0
1	1.1 (21.7)	0.3 (11.1)	
2	2.9 (58.3)	2.0 (88.9)	
3	0.5 (10.0)	0	
4	0.3 (5.0)	0	
5	0	0	
>5	0.3 (5.0)	0	
Missing	0	0	
Obesity			
N	5.0 (100.0)	2.3 (100.0)	0
Yes	1.1 (21.7)	1.0 (44.4)	
No	3.4 (68.3)	1.3 (55.6)	
Missing	0.5 (10.0)	0	
Pre-existing coagulation disorder			
N	5.0 (100.0)	2.3 (100.0)	0
Yes	0	0	
No	5.0 (100.0)	2.3 (100.0)	
Missing	0	0	

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

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Patient characteristics - by cause of PPH for matched controls - PS analysis set

	Uterine atony	Trauma	Other
Gravidity, N (%)			
N	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
1	4.6 (54.5)	1.3 (100.0)	0
2	2.3 (27.7)	0	0
3	1.0 (11.9)	0	1.0 (100.0)
4	0.3 (3.0)	0	0
5	0	0	0
>5	0.3 (3.0)	0	0
Missing	0	0	0
Obesity			
N	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
Yes	1.3 (15.8)	0	0
No	6.8 (81.2)	1.3 (100.0)	1.0 (100.0)
Missing	0.3 (3.0)	0	0
Pre-existing coagulation disorder			
N	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
Yes	0	0	0
No	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

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Patient characteristics - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention
Preeclampsia/eclampsia/HELLP, N (%)			
N	5.0 (100.0)	2.3 (100.0)	0
Yes	0	0	
No	5.0 (100.0)	2.3 (100.0)	
History of previous PPH, N (%)			
N	5.0 (100.0)	2.3 (100.0)	0
Yes	0.5 (10.0)	0	
No	4.5 (90.0)	2.3 (100.0)	
History of previous caesarean, N (%)			
N	5.0 (100.0)	2.3 (100.0)	0
Yes	2.3 (45.0)	1.0 (44.4)	
No	2.8 (55.0)	1.3 (55.6)	

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets. Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

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Patient characteristics - by cause of PPH for matched controls - PS analysis set

	Uterine atony	Trauma	Other
Preeclampsia/eclampsia/HELLP, N (%)			
N	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
Yes	0.8 (8.9)	0	0
No	7.7 (91.1)	1.3 (100.0)	1.0 (100.0)
History of previous PPH, N (%)			
N	7.8 (100.0)	1.3 (100.0)	1.0 (100.0)
Yes	0.5 (6.4)	0	0
No	7.3 (93.6)	1.3 (100.0)	1.0 (100.0)
History of previous caesarean, N (%)			
N	7.8 (100.0)	1.3 (100.0)	1.0 (100.0)
Yes	1.5 (19.1)	0	0
No	6.3 (80.9)	1.3 (100.0)	1.0 (100.0)

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets. Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

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14.1.6 Patient characteristics - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure	After first invasive procedure	Missing
1.0 Number of patients	2	0	15	1	0
Age at delivery (years), N (%)					
N	2 (100.0)	0	15 (100.0)	1 (100.0)	0
<=20	0		0	0	
21-25	0		3 (20.0)	0	
26-30	1 (50.0)		6 (40.0)	0	
31-35	1 (50.0)		4 (26.7)	1 (100.0)	
36-40	0		2 (13.3)	0	
>40	0		0	0	
Missing	0		0	0	
Gestational age at delivery, (weeks)					
N	2	0	15	1	0
Mean (SD)	32.0 (12.7)		34.1 (4.0)	36.0 (NE)	
Median (IQR)	32.0(23.0 - 41.0)		33.0(31.0 - 38.0)	36.0(36.0 - 36.0)	
Min ; Max	23 ; 41		27 ; 40	36 ; 36	
Maternal body weight, (kg)					
N	2	0	15	1	0
Mean (SD)	64.5 (6.4)		77.6 (17.7)	70.0 (NE)	
Median (IQR)	64.5(60.0 - 69.0)		72.0(63.0 - 90.0)	70.0(70.0 - 70.0)	
Min ; Max	60 ; 69		52 ; 120	70 ; 70	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure:

First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

Obesity is defined as BMI ≥ 30 . BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure	After first invasive procedure	Missing
Delivery type, N (%)					
N	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Spontaneous vaginal	0		1 (6.7)	0	
Instrumental vaginal	1 (50.0)		0	0	
I° CS	0		2 (13.3)	1 (100.0)	
II° CS	0		9 (60.0)	0	
Emergency CS	1 (50.0)		3 (20.0)	0	
Missing	0		0	0	
Cause of PPH, N (%)					
N	2 (100.0)	0	15 (100.0)	1 (100.0)	0
AIP	1 (50.0)		3 (20.0)	0	
Placental abruption	0		1 (6.7)	0	
Placental retention	0		0	0	
Uterine atony	1 (50.0)		11 (73.3)	1 (100.0)	
Trauma	0		0	0	
Other	0		0	0	
Missing	0		0	0	
Single cause	1 (50.0)		10 (66.7)	1 (100.0)	
Multiple cause	1 (50.0)		5 (33.3)	0	
Missing	0		0	0	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

Obesity is defined as BMI $\geq$ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure	After first invasive procedure	Missing
Number of babies					
N	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Singleton	2 (100.0)		10 (66.7)	1 (100.0)	
Twins	0		5 (33.3)	0	
> 2 babies	0		0	0	
Missing	0		0	0	
Parity (count)					
N	2	0	15	1	0
Mean (SD)	0.5 (0.7)		1.5 (0.8)	2.0 (NE)	
Median (IQR)	0.5(0.0 - 1.0)		1.0(1.0 - 2.0)	2.0(2.0 - 2.0)	
Min ; Max	0 ; 1		1 ; 4	2 ; 2	
Parity, N (%)					
N	2 (100.0)	0	15 (100.0)	1 (100.0)	0
0	1 (50.0)		0	0	
1	1 (50.0)		9 (60.0)	0	
2	0		5 (33.3)	1 (100.0)	
3	0		0	0	
4	0		1 (6.7)	0	
5	0		0	0	
>5	0		0	0	
Missing	0		0	0	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

Obesity is defined as BMI $\geq$ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure	After first invasive procedure	Missing
Gravidity (count)					
N	2	0	15	1	0
Mean (SD)	1.5 (0.7)		1.5 (0.7)	2.0 (NE)	
Median (IQR)	1.5 (1.0 - 2.0)		1.0 (1.0 - 2.0)	2.0 (2.0 - 2.0)	
Min ; Max	1 ; 2		1 ; 3	2 ; 2	
Gravidity, N (%)					
N	2 (100.0)	0	15 (100.0)	1 (100.0)	0
1	1 (50.0)		9 (60.0)	0	
2	1 (50.0)		4 (26.7)	1 (100.0)	
3	0		2 (13.3)	0	
4	0		0	0	
5	0		0	0	
>5	0		0	0	
Missing	0		0	0	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

Obesity is defined as BMI $\geq$ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure	After first invasive procedure	Missing
Obesity					
N	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Yes	0		6 (40.0)	0	
No	2 (100.0)		8 (53.3)	1 (100.0)	
Missing	0		1 (6.7)	0	
Pre-existing coagulation disorder					
N	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Yes	1 (50.0)		1 (6.7)	0	
No	1 (50.0)		14 (93.3)	1 (100.0)	
Missing	0		0	0	
Preeclampsia/eclampsia/HELLP, N (%)					
N	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Yes	0		2 (13.3)	0	
No	2 (100.0)		13 (86.7)	1 (100.0)	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

Obesity is defined as BMI ≥ 30 . BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure	After first invasive procedure	Missing
History of previous PPH, N (%)					
N	2 (100.0)	0	14 (100.0)	1 (100.0)	0
Yes	0		1 (7.1)	0	
No	2 (100.0)		13 (92.9)	1 (100.0)	
History of previous caesarean, N (%)					
N	2 (100.0)	0	14 (100.0)	1 (100.0)	0
Yes	0		1 (7.1)	0	
No	2 (100.0)		13 (92.9)	1 (100.0)	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure:

First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

Obesity is defined as BMI ≥ 30 . BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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14.1.7 Patient characteristics - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Number of patients	4	14
Age at delivery (years), N (%)		
N	4 (100.0)	14 (100.0)
<=20	0	0
21-25	0	3 (21.4)
26-30	2 (50.0)	5 (35.7)
31-35	2 (50.0)	4 (28.6)
36-40	0	2 (14.3)
>40	0	0
Missing	0	0
Gestational age at delivery, (weeks)		
N	4	14
Mean (SD)	31.5 (3.4)	34.7 (5.1)
Median (IQR)	32.0 (29.0 - 34.0)	36.5 (31.0 - 38.0)
Min ; Max	27 ; 35	23 ; 41
Maternal body weight, (kg)		
N	4	14
Mean (SD)	81.6 (13.6)	74.1 (17.6)
Median (IQR)	86.3 (72.5 - 90.8)	70.0 (63.0 - 81.0)
Min ; Max	62 ; 92	52 ; 120

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Delivery type, N (%)		
N	4 (100.0)	14 (100.0)
Spontaneous vaginal	0	1 (7.1)
Instrumental vaginal	0	1 (7.1)
I° CS	0	3 (21.4)
II° CS	3 (75.0)	6 (42.9)
Emergency CS	1 (25.0)	3 (21.4)
Missing	0	0
Cause of PPH, N (%)		
N	4 (100.0)	14 (100.0)
AIP	0	4 (28.6)
Placental abruption	1 (25.0)	0
Placental retention	0	0
Uterine atony	3 (75.0)	10 (71.4)
Trauma	0	0
Other	0	0
Missing	0	0
Single cause	4 (100.0)	8 (57.1)
Multiple cause	0	6 (42.9)
Missing	0	0
Number of babies		
N	4 (100.0)	14 (100.0)
Singleton	1 (25.0)	12 (85.7)
Twins	3 (75.0)	2 (14.3)
> 2 babies	0	0
Missing	0	0

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.
Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.
One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Parity (count)		
N	4	14
Mean (SD)	2.0 (1.4)	1.3 (0.6)
Median (IQR)	1.5(1.0 - 3.0)	1.0(1.0 - 2.0)
Min ; Max	1 ; 4	0 ; 2
Parity, N (%)		
N	4 (100.0)	14 (100.0)
0	0	1 (7.1)
1	2 (50.0)	8 (57.1)
2	1 (25.0)	5 (35.7)
3	0	0
4	1 (25.0)	0
5	0	0
>5	0	0
Missing	0	0
Gravidity (count)		
N	4	14
Mean (SD)	2.0 (0.8)	1.4 (0.6)
Median (IQR)	2.0(1.5 - 2.5)	1.0(1.0 - 2.0)
Min ; Max	1 ; 3	1 ; 3

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.
Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.
One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Gravidity, N (%)		
N	4 (100.0)	14 (100.0)
1	1 (25.0)	9 (64.3)
2	2 (50.0)	4 (28.6)
3	1 (25.0)	1 (7.1)
4	0	0
5	0	0
>5	0	0
Missing	0	0
Obesity		
N	4 (100.0)	14 (100.0)
Yes	2 (50.0)	4 (28.6)
No	2 (50.0)	9 (64.3)
Missing	0	1 (7.1)
Pre-existing coagulation disorder		
N	4 (100.0)	14 (100.0)
Yes	0	2 (14.3)
No	4 (100.0)	12 (85.7)
Missing	0	0

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Preeclampsia/eclampsia/HELLP, N (%)		
N	4 (100.0)	14 (100.0)
Yes	1 (25.0)	1 (7.1)
No	3 (75.0)	13 (92.9)
History of previous PPH, N (%)		
N	4 (100.0)	13 (100.0)
Yes	0	1 (7.7)
No	4 (100.0)	12 (92.3)
History of previous caesarean, N (%)		
N	4 (100.0)	13 (100.0)
Yes	1 (25.0)	0
No	3 (75.0)	13 (100.0)

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.
Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.
One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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14.1.8 Patient characteristics - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Number of patients	2	16	0
Age at delivery (years), N (%)			
N	2 (100.0)	16 (100.0)	0
<=20	0	0	
21-25	0	3 (18.8)	
26-30	0	7 (43.8)	
31-35	2 (100.0)	4 (25.0)	
36-40	0	2 (12.5)	
>40	0	0	
Missing	0	0	
Gestational age at delivery, (weeks)			
N	2	16	0
Mean (SD)	33.5 (3.5)	34.1 (5.1)	
Median (IQR)	33.5 (31.0 - 36.0)	34.0 (31.0 - 38.0)	
Min ; Max	31 ; 36	23 ; 41	
Maternal body weight, (kg)			
N	2	16	0
Mean (SD)	81.0 (15.6)	75.1 (17.3)	
Median (IQR)	81.0 (70.0 - 92.0)	70.0 (62.5 - 86.3)	
Min ; Max	70 ; 92	52 ; 120	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Delivery type, N (%)			
N	2 (100.0)	16 (100.0)	0
Spontaneous vaginal	0	1 (6.3)	
Instrumental vaginal	0	1 (6.3)	
I° CS	1 (50.0)	2 (12.5)	
II° CS	0	9 (56.3)	
Emergency CS	1 (50.0)	3 (18.8)	
Missing	0	0	
Cause of PPH, N (%)			
N	2 (100.0)	16 (100.0)	0
AIP	0	4 (25.0)	
Placental abruption	1 (50.0)	0	
Placental retention	0	0	
Uterine atony	1 (50.0)	12 (75.0)	
Trauma	0	0	
Other	0	0	
Missing	0	0	
Single cause	2 (100.0)	10 (62.5)	
Multiple cause	0	6 (37.5)	
Missing	0	0	
Number of babies			
N	2 (100.0)	16 (100.0)	0
Singleton	2 (100.0)	11 (68.8)	
Twins	0	5 (31.3)	
> 2 babies	0	0	
Missing	0	0	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI ≥ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Parity (count)			
N	2	16	0
Mean (SD)	3.0 (1.4)	1.3 (0.6)	
Median (IQR)	3.0 (2.0 - 4.0)	1.0 (1.0 - 2.0)	
Min ; Max	2 ; 4	0 ; 2	
Parity, N (%)			
N	2 (100.0)	16 (100.0)	0
0	0	1 (6.3)	
1	0	10 (62.5)	
2	1 (50.0)	5 (31.3)	
3	0	0	
4	1 (50.0)	0	
5	0	0	
>5	0	0	
Missing	0	0	
Gravidity (count)			
N	2	16	0
Mean (SD)	2.0 (0.0)	1.5 (0.7)	
Median (IQR)	2.0 (2.0 - 2.0)	1.0 (1.0 - 2.0)	
Min ; Max	2 ; 2	1 ; 3	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Gravidity, N (%)			
N	2 (100.0)	16 (100.0)	0
1	0	10 (62.5)	
2	2 (100.0)	4 (25.0)	
3	0	2 (12.5)	
4	0	0	
5	0	0	
>5	0	0	
Missing	0	0	
Obesity			
N	2 (100.0)	16 (100.0)	0
Yes	1 (50.0)	5 (31.3)	
No	1 (50.0)	10 (62.5)	
Missing	0	1 (6.3)	
Pre-existing coagulation disorder			
N	2 (100.0)	16 (100.0)	0
Yes	0	2 (12.5)	
No	2 (100.0)	14 (87.5)	
Missing	0	0	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI ≥ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Preeclampsia/eclampsia/HELLP, N (%)			
N	2 (100.0)	16 (100.0)	0
Yes	1 (50.0)	1 (6.3)	
No	1 (50.0)	15 (93.8)	
History of previous PPH, N (%)			
N	2 (100.0)	15 (100.0)	0
Yes	0	1 (6.7)	
No	2 (100.0)	14 (93.3)	
History of previous caesarean, N (%)			
N	2 (100.0)	15 (100.0)	0
Yes	1 (50.0)	0	
No	1 (50.0)	15 (100.0)	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI ≥ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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14.1.9 Patient characteristics - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	2	11	5	0
Age at delivery (years), N (%)				
N	2 (100.0)	11 (100.0)	5 (100.0)	0
≤20	0	0	0	
21-25	0	1 (9.1)	2 (40.0)	
26-30	1 (50.0)	3 (27.3)	3 (60.0)	
31-35	1 (50.0)	5 (45.5)	0	
36-40	0	2 (18.2)	0	
>40	0	0	0	
Missing	0	0	0	
Gestational age at delivery, (weeks)				
N	2	11	5	0
Mean (SD)	25.0 (2.8)	33.2 (2.6)	39.4 (1.3)	
Median (IQR)	25.0 (23.0 - 27.0)	33.0 (31.0 - 36.0)	40.0 (38.0 - 40.0)	
Min ; Max	23 ; 27	30 ; 37	38 ; 41	
Maternal body weight, (kg)				
N	2	11	5	0
Mean (SD)	76.0 (9.9)	73.5 (15.3)	80.6 (23.3)	
Median (IQR)	76.0 (69.0 - 83.0)	70.0 (62.0 - 90.0)	72.0 (70.0 - 81.0)	
Min ; Max	69 ; 83	52 ; 95	60 ; 120	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI ≥ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Delivery type, N (%)				
N	2 (100.0)	11 (100.0)	5 (100.0)	0
Spontaneous vaginal	0	1 (9.1)	0	
Instrumental vaginal	0	0	1 (20.0)	
I° CS	0	2 (18.2)	1 (20.0)	
II° CS	1 (50.0)	6 (54.5)	2 (40.0)	
Emergency CS	1 (50.0)	2 (18.2)	1 (20.0)	
Missing	0	0	0	
Cause of PPH, N (%)				
N	2 (100.0)	11 (100.0)	5 (100.0)	0
AIP	0	3 (27.3)	1 (20.0)	
Placental abruption	0	1 (9.1)	0	
Placental retention	0	0	0	
Uterine atony	2 (100.0)	7 (63.6)	4 (80.0)	
Trauma	0	0	0	
Other	0	0	0	
Missing	0	0	0	
Single cause	2 (100.0)	7 (63.6)	3 (60.0)	
Multiple cause	0	4 (36.4)	2 (40.0)	
Missing	0	0	0	
Number of babies				
N	2 (100.0)	11 (100.0)	5 (100.0)	0
Singleton	1 (50.0)	8 (72.7)	4 (80.0)	
Twins	1 (50.0)	3 (27.3)	1 (20.0)	
> 2 babies	0	0	0	
Missing	0	0	0	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI $\geq$ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Parity (count)				
N	2	11	5	0
Mean (SD)	1.0 (1.4)	1.6 (0.9)	1.2 (0.4)	
Median (IQR)	1.0 (0.0 - 2.0)	1.0 (1.0 - 2.0)	1.0 (1.0 - 1.0)	
Min ; Max	0 ; 2	1 ; 4	1 ; 2	
Parity, N (%)				
N	2 (100.0)	11 (100.0)	5 (100.0)	0
0	1 (50.0)	0	0	
1	0	6 (54.5)	4 (80.0)	
2	1 (50.0)	4 (36.4)	1 (20.0)	
3	0	0	0	
4	0	1 (9.1)	0	
5	0	0	0	
>5	0	0	0	
Missing	0	0	0	
Gravidity (count)				
N	2	11	5	0
Mean (SD)	2.0 (1.4)	1.5 (0.5)	1.6 (0.9)	
Median (IQR)	2.0 (1.0 - 3.0)	1.0 (1.0 - 2.0)	1.0 (1.0 - 2.0)	
Min ; Max	1 ; 3	1 ; 2	1 ; 3	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Gravidity, N (%)				
N	2 (100.0)	11 (100.0)	5 (100.0)	0
1	1 (50.0)	6 (54.5)	3 (60.0)	
2	0	5 (45.5)	1 (20.0)	
3	1 (50.0)	0	1 (20.0)	
4	0	0	0	
5	0	0	0	
>5	0	0	0	
Missing	0	0	0	
Obesity				
N	2 (100.0)	11 (100.0)	5 (100.0)	0
Yes	0	4 (36.4)	2 (40.0)	
No	2 (100.0)	6 (54.5)	3 (60.0)	
Missing	0	1 (9.1)	0	
Pre-existing coagulation disorder				
N	2 (100.0)	11 (100.0)	5 (100.0)	0
Yes	1 (50.0)	1 (9.1)	0	
No	1 (50.0)	10 (90.9)	5 (100.0)	
Missing	0	0	0	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI $\geq$ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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Patient characteristics - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Preeclampsia/eclampsia/HELLP, N (%)				
N	2 (100.0)	11 (100.0)	5 (100.0)	0
Yes	0	2 (18.2)	0	
No	2 (100.0)	9 (81.8)	5 (100.0)	
History of previous PPH, N (%)				
N	2 (100.0)	11 (100.0)	4 (100.0)	0
Yes	0	1 (9.1)	0	
No	2 (100.0)	10 (90.9)	4 (100.0)	
History of previous caesarean, N (%)				
N	2 (100.0)	11 (100.0)	4 (100.0)	0
Yes	0	1 (9.1)	0	
No	2 (100.0)	10 (90.9)	4 (100.0)	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI ≥ 30 . BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

One patient have parity as 0 due to sPPH onset was before deliver of the womans first child.

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14.1.10 Patient characteristics - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	1	26	16	0
Number of weighted patients, N	0.3	8.1	9.7	0
Age at delivery (years), N (%)				
N	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
<=20	0	0	0.3 (3.4)	
21-25	0.3 (100.0)	0.7 (8.2)	1.0 (10.3)	
26-30	0	1.8 (22.7)	1.3 (12.9)	
31-35	0	1.5 (18.6)	2.8 (28.4)	
36-40	0	2.8 (34.0)	4.3 (44.8)	
>40	0	1.3 (16.5)	0	
Missing	0	0	0	
Gestational age at delivery, (weeks)				
N	0.3	8.1	9.7	0
Mean (SD)	26.0 (NE)	32.7 (1.2)	39.6 (0.9)	
Median (IQR)	26.0 (26.0 - 26.0)	33.0 (31.0 - 34.0)	40.0 (39.0 - 40.0)	
Min ; Max	26 ; 26	29 ; 36	38 ; 42	
Maternal body weight, (kg)				
N	0.3	8.1	9.7	0
Mean (SD)	70.0 (NE)	68.0 (5.6)	76.5 (13.4)	
Median (IQR)	70.0 (70.0 - 70.0)	70.0 (63.0 - 71.0)	70.0 (64.0 - 81.0)	
Min ; Max	70 ; 70	51 ; 95	60 ; 115	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

/fvii/nn7711-4729/ctr_20210821_er
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Patient characteristics - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Delivery type, N (%)				
N	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
Spontaneous vaginal	0	0.5 (6.2)	0.5 (5.2)	
Instrumental vaginal	0	0	1.0 (10.3)	
I° CS	0	4.3 (52.6)	0	
II° CS	0	2.3 (27.8)	4.1 (42.2)	
Emergency CS	0.3 (100.0)	1.1 (13.4)	4.1 (42.2)	
Missing	0	0	0	
Cause of PPH, N (%)				
N	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
AIP	0.3 (100.0)	4.3 (52.6)	0.5 (5.2)	
Placental abruption	0	0.3 (3.1)	2.0 (20.7)	
Placental retention	0	0	0	
Uterine atony	0	3.3 (40.2)	5.2 (53.4)	
Trauma	0	0.3 (4.1)	1.0 (10.3)	
Other	0	0	1.0 (10.3)	
Missing	0	0	0	
Single cause	0.3 (100.0)	4.3 (52.6)	8.2 (84.5)	
Multiple cause	0	3.8 (47.4)	1.5 (15.5)	
Missing	0	0	0	
Number of babies				
N	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
Singleton	0.3 (100.0)	6.5 (80.4)	9.7 (100.0)	
Twins	0	1.3 (16.5)	0	
> 2 babies	0	0.3 (3.1)	0	
Missing	0	0	0	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI $\geq$ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

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Patient characteristics - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Parity (count)				
N	0.3	8.1	9.7	0
Mean (SD)	2.0 (NE)	2.0 (0.6)	1.5 (0.5)	
Median (IQR)	2.0 (2.0 - 2.0)	2.0 (1.0 - 2.0)	1.0 (1.0 - 2.0)	
Min ; Max	2 ; 2	1 ; 6	1 ; 3	
Parity, N (%)				
N	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
0	0	0	0	
1	0	3.0 (37.1)	5.1 (52.6)	
2	0.3 (100.0)	3.6 (44.3)	4.1 (42.2)	
3	0	1.0 (12.4)	0.5 (5.2)	
4	0	0	0	
5	0	0.3 (3.1)	0	
>5	0	0.3 (3.1)	0	
Missing	0	0	0	
Gravidity (count)				
N	0.3	8.1	9.7	0
Mean (SD)	4.0 (NE)	2.0 (0.8)	1.8 (0.6)	
Median (IQR)	4.0 (4.0 - 4.0)	2.0 (1.0 - 2.0)	2.0 (1.0 - 2.0)	
Min ; Max	4 ; 4	1 ; 7	1 ; 3	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

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Patient characteristics - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Gravidity, N (%)				
N	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
1	0	3.2 (39.2)	4.1 (42.2)	
2	0	3.4 (42.3)	3.8 (39.7)	
3	0	0.8 (9.3)	1.8 (18.1)	
4	0.3 (100.0)	0.3 (3.1)	0	
5	0	0	0	
>5	0	0.5 (6.2)	0	
Missing	0	0	0	
Obesity				
N	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
Yes	0.3 (100.0)	1.3 (16.5)	1.8 (19.0)	
No	0	6.0 (74.2)	7.8 (81.0)	
Missing	0	0.8 (9.3)	0	
Pre-existing coagulation disorder				
N	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
Yes	0	0	0	
No	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	
Missing	0	0	0	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI $\geq$ 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

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Patient characteristics - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Preeclampsia/eclampsia/HELLP, N (%)				
N	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
Yes	0	0.8 (9.3)	0	
No	0.3 (100.0)	7.3 (90.7)	9.7 (100.0)	
History of previous PPH, N (%)				
N	0.3 (100.0)	8.1 (100.0)	9.1 (100.0)	0
Yes	0	0.5 (6.2)	0.5 (5.5)	
No	0.3 (100.0)	7.6 (93.8)	8.6 (94.5)	
History of previous caesarean, N (%)				
N	0.3 (100.0)	8.1 (100.0)	9.1 (100.0)	0
Yes	0.3 (100.0)	2.8 (34.0)	1.8 (19.3)	
No	0	5.3 (66.0)	7.3 (80.7)	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), AIP: Abnormally invasive placenta (including praevia), CS: Caesarean section, I° CS: CS before start of delivery, i.e. an elective CS, II° CS: CS was performed after start of contractions or rupture of membranes, PPH: Postpartum haemorrhage, NE: Not Estimable, HELLP: Hemolysis, Elevated Liver enzymes and Low Platelets.

Obesity is defined as BMI >= 30. BMI (body mass index) is calculated based on the weight recorded in the surgery chart.

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14.1.11 Concomitant medications - full analysis set

PS analysis set		
	NovoSeven®	Matched controls
1.0 Number of patients	18	43
Number of weighted patients, N		18.0
Tranexamic acid from delivery to time0, N (%)		
Yes	10 (55.6)	8.0 (44.4)
No	8 (44.4)	10.0 (55.6)
Tranexamic acid from time0 until 24 hours after time0, N (%)		
Yes	3 (16.7)	7.9 (43.9)
No	15 (83.3)	10.1 (56.1)
Tranexamic acid overall*, N (%)		
Yes	13 (72.2)	13.9 (77.2)
No	5 (27.8)	4.1 (22.8)
Fibrinogen from delivery to time0, N (%)		
Yes	6 (33.3)	2.6 (14.4)
No	12 (66.7)	15.4 (85.6)
Fibrinogen from time0 until 24 hours after time0, N (%)		
Yes	3 (16.7)	3.6 (20.0)
No	15 (83.3)	14.4 (80.0)

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, PLT: platelet.

*Overall is measured in the period from delivery to stop of PPH.

Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses. Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - full analysis set

Full analysis set			
	NovoSeven®	No NovoSeven®	Total
1.0 Number of patients	52	113	165
Number of weighted patients, N			
Tranexamic acid from delivery to time0, N (%)			
Yes	32 (61.5)		
No	20 (38.5)		
Tranexamic acid from time0 until 24 hours after time0, N (%)			
Yes	6 (11.5)		
No	46 (88.5)		
Tranexamic acid overall*, N (%)			
Yes	37 (71.2)	85 (75.2)	122 (73.9)
No	15 (28.8)	28 (24.8)	43 (26.1)
Fibrinogen from delivery to time0, N (%)			
Yes	14 (26.9)		
No	38 (73.1)		
Fibrinogen from time0 until 24 hours after time0, N (%)			
Yes	9 (17.3)		
No	43 (82.7)		

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, PLT: platelet.

*Overall is measured in the period from delivery to stop of PPH.

Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses. Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Trial ID: NN7711-4729

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Novo Nordisk

Concomitant medications - full analysis set

PS analysis set

NovoSeven®

Matched controls

Fibrinogen overall*, N (%)

Yes	8 (44.4)	5.9 (32.8)
No	10 (55.6)	12.1 (67.2)

Oxytocin from delivery to time0 (count)

N	16	15.2
Mean (SD)	2.3 (1.3)	2.2 (0.9)
Median (IQR)	2.0 (1.0 - 3.0)	2.0 (1.0 - 3.0)
Min ; Max	1 ; 6	1 ; 6

Oxytocin from time0 until 24 hours after time0 (count)

N	9	8.3
Mean (SD)	1.1 (0.3)	1.6 (0.5)
Median (IQR)	1.0 (1.0 - 1.0)	1.0 (1.0 - 2.0)
Min ; Max	1 ; 2	1 ; 4

Oxytocin overall* (count)

N	16	16.2
Mean (SD)	2.6 (1.4)	2.8 (1.1)
Median (IQR)	2.5 (1.5 - 3.0)	3.0 (1.0 - 4.0)
Min ; Max	1 ; 6	1 ; 6

Other uterotonics from delivery to time0 (count)

N	15	11.9
Mean (SD)	1.7 (0.8)	1.8 (0.7)
Median (IQR)	2.0 (1.0 - 2.0)	1.0 (1.0 - 2.0)
Min ; Max	1 ; 4	1 ; 4

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, PLT: platelet.

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Concomitant medications - full analysis set

Full analysis set			
	NovoSeven®	No NovoSeven®	Total
Fibrinogen overall*, N (%)			
Yes	19 (36.5)	23 (20.4)	42 (25.5)
No	33 (63.5)	90 (79.6)	123 (74.5)
Oxytocin from delivery to time0 (count)			
N	45		
Mean (SD)	2.2 (1.3)		
Median (IQR)	2.0 (1.0 - 3.0)		
Min ; Max	1 ; 6		
Oxytocin from time0 until 24 hours after time0 (count)			
N	19		
Mean (SD)	1.6 (1.4)		
Median (IQR)	1.0 (1.0 - 2.0)		
Min ; Max	1 ; 7		
Oxytocin overall* (count)			
N	46	84	130
Mean (SD)	2.4 (1.2)	1.8 (1.0)	2.0 (1.1)
Median (IQR)	2.0 (1.0 - 3.0)	2.0 (1.0 - 2.0)	2.0 (1.0 - 3.0)
Min ; Max	1 ; 6	1 ; 6	1 ; 6
Other uterotonics from delivery to time0 (count)			
N	40		
Mean (SD)	1.9 (0.9)		
Median (IQR)	2.0 (1.0 - 2.0)		
Min ; Max	1 ; 4		

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, PLT: platelet.

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Matched controls

Other uterotonics from time0 until 24 hours after time0 (count)

N	9	6.8
Mean (SD)	1.3 (0.5)	1.4 (0.4)
Median (IQR)	1.0 (1.0 - 2.0)	1.0 (1.0 - 2.0)
Min ; Max	1 ; 2	1 ; 3

Other uterotonics overall* (count)

N	17	13.4
Mean (SD)	2.1 (0.8)	2.2 (0.6)
Median (IQR)	2.0 (2.0 - 2.0)	2.0 (2.0 - 3.0)
Min ; Max	1 ; 4	1 ; 4

Colloids from delivery to time0 (mL)

N	14	16.0
Mean (SD)	1178.6 (668.2)	1169.3 (465.1)
Median (IQR)	1000.0 (500.0 - 1500.0)	1000.0 (500.0 - 1750.0)
Min ; Max	500 ; 2500	500 ; 2500

Colloids from time0 until 24 hours after time0 (mL)

N	5	8.9
Mean (SD)	600.0 (223.6)	967.3 (382.7)
Median (IQR)	500.0 (500.0 - 500.0)	500.0 (500.0 - 1500.0)
Min ; Max	500 ; 1000	500 ; 2500

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Concomitant medications - full analysis set

Full analysis set			
	NovoSeven®	No NovoSeven®	Total
Other uterotonics from time0 until 24 hours after time0 (count)			
N	15		
Mean (SD)	1.2 (0.4)		
Median (IQR)	1.0 (1.0 - 1.0)		
Min ; Max	1 ; 2		
Other uterotonics overall* (count)			
N	42	80	122
Mean (SD)	2.1 (0.9)	1.8 (1.0)	1.9 (0.9)
Median (IQR)	2.0 (1.0 - 3.0)	2.0 (1.0 - 2.0)	2.0 (1.0 - 2.0)
Min ; Max	1 ; 4	1 ; 5	1 ; 5
Colloids from delivery to time0 (mL)			
N	45		
Mean (SD)	1300.0 (779.0)		
Median (IQR)	1000.0 (500.0 - 2000.0)		
Min ; Max	500 ; 3500		
Colloids from time0 until 24 hours after time0 (mL)			
N	8		
Mean (SD)	625.0 (231.5)		
Median (IQR)	500.0 (500.0 - 750.0)		
Min ; Max	500 ; 1000		

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, PLT: platelet.

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Matched controls

Colloids overall* (mL)

N	15	16.8
Mean (SD)	1300.0 (702.0)	1699.0 (661.1)
Median (IQR)	1000.0 (500.0 - 2000.0)	1500.0 (1000.0 - 2500.0)
Min ; Max	500 ; 2500	500 ; 4000

Crystalloids from delivery to time0 (mL)

N	15	16.9
Mean (SD)	1733.3 (1148.7)	2136.7 (894.7)
Median (IQR)	1500.0 (1000.0 - 2500.0)	2400.0 (1000.0 - 2700.0)
Min ; Max	500 ; 4500	500 ; 7000

Crystalloids from time0 until 24 hours after time0 (mL)

N	13	15.1
Mean (SD)	1630.8 (705.5)	2000.8 (911.6)
Median (IQR)	1300.0 (1000.0 - 2000.0)	1600.0 (1000.0 - 2850.0)
Min ; Max	1000 ; 3000	100 ; 8000

Crystalloids overall* (mL)

N	16	17.4
Mean (SD)	2353.1 (1215.1)	3471.8 (1063.0)
Median (IQR)	2125.0 (1500.0 - 3400.0)	3400.0 (2500.0 - 4400.0)
Min ; Max	500 ; 4500	500 ; 7000

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Concomitant medications - full analysis set

Full analysis set			
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Colloids overall* (mL)			
N	46	69	115
Mean (SD)	1369.6 (805.8)	979.0 (714.6)	1135.2 (773.2)
Median (IQR)	1000.0 (500.0 - 2000.0)	500.0 (500.0 - 1000.0)	1000.0 (500.0 - 1500.0)
Min ; Max	500 ; 3500	350 ; 4000	350 ; 4000
Crystalloids from delivery to time0 (mL)			
N	48		
Mean (SD)	2438.5 (1455.9)		
Median (IQR)	2100.0 (1225.0 - 3500.0)		
Min ; Max	500 ; 7000		
Crystalloids from time0 until 24 hours after time0 (mL)			
N	29		
Mean (SD)	1791.4 (721.2)		
Median (IQR)	1500.0 (1200.0 - 2000.0)		
Min ; Max	1000 ; 3500		
Crystalloids overall* (mL)			
N	50	100	150
Mean (SD)	2969.0 (1695.9)	2078.8 (1469.7)	2375.5 (1599.5)
Median (IQR)	2800.0 (1500.0 - 4000.0)	2000.0 (1000.0 - 2800.0)	2000.0 (1000.0 - 3500.0)
Min ; Max	500 ; 7000	100 ; 6660	100 ; 7000

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Concomitant medications - full analysis set

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Matched controls

Red blood cells from delivery to time0 (count)

N	16	14.3
Mean (SD)	4.3 (2.9)	4.4 (1.7)
Median (IQR)	4.0 (2.0 - 6.0)	4.0 (2.0 - 6.0)
Min ; Max	1 ; 10	1 ; 10

Red blood cells from time0 until 24 hours after time0 (count)

N	15	16.4
Mean (SD)	7.1 (5.1)	8.1 (3.5)
Median (IQR)	6.0 (3.0 - 10.0)	7.0 (4.0 - 11.0)
Min ; Max	1 ; 20	1 ; 23

Red blood cells overall* (count)

N	18	17.5
Mean (SD)	9.7 (6.8)	10.8 (4.5)
Median (IQR)	8.5 (6.0 - 12.0)	10.0 (6.0 - 13.0)
Min ; Max	1 ; 29	1 ; 29

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, PLT: platelet.

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Concomitant medications - full analysis set

Full analysis set			
	NovoSeven®	No NovoSeven®	Total
Red blood cells from delivery to time0 (count)			
N	48		
Mean (SD)	6.9 (4.1)		
Median (IQR)	6.0 (4.0 - 10.0)		
Min ; Max	1 ; 17		
Red blood cells from time0 until 24 hours after time0 (count)			
N	39		
Mean (SD)	6.8 (4.5)		
Median (IQR)	5.0 (3.0 - 10.0)		
Min ; Max	1 ; 20		
Red blood cells overall* (count)			
N	51	58	109
Mean (SD)	11.1 (6.7)	4.1 (3.5)	7.4 (6.3)
Median (IQR)	10.0 (6.0 - 14.0)	3.0 (2.0 - 6.0)	6.0 (2.0 - 11.0)
Min ; Max	1 ; 30	1 ; 18	1 ; 30

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Matched controls

Red blood cells from delivery to time0 (mL)

N	16	14.3
Mean (SD)	1185.9 (795.2)	1211.0 (467.7)
Median (IQR)	1100.0 (550.0 - 1650.0)	1100.0 (550.0 - 1650.0)
Min ; Max	275 ; 2750	275 ; 2750

Red blood cells from time0 until 24 hours after time0 (mL)

N	15	16.4
Mean (SD)	1961.7 (1401.7)	2219.5 (960.1)
Median (IQR)	1650.0 (825.0 - 2750.0)	1925.0 (1100.0 - 3025.0)
Min ; Max	275 ; 5500	275 ; 6325

Red blood cells overall* (mL)

N	18	17.5
Mean (SD)	2673.6 (1869.4)	2983.1 (1233.6)
Median (IQR)	2337.5 (1650.0 - 3300.0)	2750.0 (1650.0 - 3575.0)
Min ; Max	275 ; 7975	275 ; 7975

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, PLT: platelet.

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Concomitant medications - full analysis set

Full analysis set

	NovoSeven®	No NovoSeven®	Total
Red blood cells from delivery to time0 (mL)			
N	48		
Mean (SD)	1907.8 (1133.7)		
Median (IQR)	1650.0 (1100.0 - 2750.0)		
Min ; Max	275 ; 4675		
Red blood cells from time0 until 24 hours after time0 (mL)			
N	39		
Mean (SD)	1861.5 (1246.7)		
Median (IQR)	1375.0 (825.0 - 2750.0)		
Min ; Max	275 ; 5500		
Red blood cells overall* (mL)			
N	51	58	109
Mean (SD)	3041.2 (1852.5)	1128.4 (950.8)	2023.4 (1727.7)
Median (IQR)	2750.0 (1650.0 - 3850.0)	825.0 (550.0 - 1650.0)	1650.0 (550.0 - 3025.0)
Min ; Max	275 ; 8250	275 ; 4950	275 ; 8250

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FFP transfusion from delivery to time0 (count)

N	14	13.7
Mean (SD)	4.4 (3.0)	4.0 (1.8)
Median (IQR)	3.5 (2.0 - 6.0)	4.0 (3.0 - 4.0)
Min ; Max	1 ; 10	1 ; 10

FFP transfusion from time0 until 24 hours after time0 (count)

N	17	14.3
Mean (SD)	5.9 (5.9)	7.2 (3.2)
Median (IQR)	4.0 (2.0 - 7.0)	7.0 (5.0 - 9.0)
Min ; Max	1 ; 23	1 ; 26

FFP transfusion overall* (count)

N	18	16.7
Mean (SD)	8.8 (7.1)	9.5 (4.2)
Median (IQR)	8.0 (4.0 - 10.0)	9.0 (5.0 - 12.0)
Min ; Max	1 ; 32	2 ; 32

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, PLT: platelet.

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Concomitant medications - full analysis set

Full analysis set			
	NovoSeven®	No NovoSeven®	Total
FFP transfusion from delivery to time0 (count)			
N	45		
Mean (SD)	6.0 (3.2)		
Median (IQR)	5.0 (4.0 - 8.0)		
Min ; Max	1 ; 14		
FFP transfusion from time0 until 24 hours after time0 (count)			
N	40		
Mean (SD)	6.0 (4.9)		
Median (IQR)	4.5 (3.0 - 8.0)		
Min ; Max	1 ; 23		
FFP transfusion overall* (count)			
N	50	46	96
Mean (SD)	9.7 (6.5)	3.6 (2.8)	6.8 (5.9)
Median (IQR)	8.0 (5.0 - 12.0)	2.0 (2.0 - 5.0)	5.0 (2.0 - 9.5)
Min ; Max	1 ; 32	1 ; 12	1 ; 32

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, PLT: platelet.

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FFP transfusion from delivery to time0 (mL)

N	14	13.7
Mean (SD)	1220.0 (840.8)	1132.0 (494.2)
Median (IQR)	980.0 (560.0 - 1680.0)	1120.0 (840.0 - 1120.0)
Min ; Max	280 ; 2800	280 ; 2800

FFP transfusion from time0 until 24 hours after time0 (mL)

N	17	14.3
Mean (SD)	1647.1 (1656.2)	2015.7 (899.3)
Median (IQR)	1120.0 (560.0 - 1960.0)	1960.0 (1400.0 - 2520.0)
Min ; Max	280 ; 6440	280 ; 7280

FFP transfusion overall* (mL)

N	18	16.7
Mean (SD)	2457.8 (1995.1)	2660.0 (1186.3)
Median (IQR)	2240.0 (1120.0 - 2800.0)	2520.0 (1400.0 - 3360.0)
Min ; Max	280 ; 8960	560 ; 8960

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, PLT: platelet.

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Full analysis set

	NovoSeven®	No NovoSeven®	Total
FFP transfusion from delivery to time0 (mL)			
N	45		
Mean (SD)	1667.6 (895.4)		
Median (IQR)	1400.0 (1120.0 - 2240.0)		
Min ; Max	280 ; 3920		
FFP transfusion from time0 until 24 hours after time0 (mL)			
N	40		
Mean (SD)	1673.0 (1385.5)		
Median (IQR)	1260.0 (840.0 - 2240.0)		
Min ; Max	280 ; 6440		
FFP transfusion overall* (mL)			
N	50	46	96
Mean (SD)	2710.4 (1820.3)	1010.4 (777.5)	1895.8 (1650.5)
Median (IQR)	2240.0 (1400.0 - 3360.0)	560.0 (560.0 - 1400.0)	1400.0 (560.0 - 2660.0)
Min ; Max	280 ; 8960	280 ; 3360	280 ; 8960

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, PLT: platelet.

*Overall is measured in the period from delivery to stop of PPH.

Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses. Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - full analysis set

PS analysis set

NovoSeven®

Matched controls

Platelets from delivery to time0 (count)

N	4	3.5
Mean (SD)	1.0 (0.0)	1.0 (0.0)
Median (IQR)	1.0 (1.0 - 1.0)	1.0 (1.0 - 1.0)
Min ; Max	1 ; 1	1 ; 1

Platelets from time0 until 24 hours after time0 (count)

N	8	9.7
Mean (SD)	1.5 (0.8)	2.0 (0.6)
Median (IQR)	1.0 (1.0 - 2.0)	2.0 (1.0 - 3.0)
Min ; Max	1 ; 3	1 ; 3

Platelets overall* (count)

N	10	10.3
Mean (SD)	1.5 (0.8)	2.1 (0.7)
Median (IQR)	1.0 (1.0 - 2.0)	2.0 (1.0 - 3.0)
Min ; Max	1 ; 3	1 ; 4

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, PLT: platelet.

*Overall is measured in the period from delivery to stop of PPH.

Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses. Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - full analysis set

Full analysis set			
	NovoSeven®	No NovoSeven®	Total
Platelets from delivery to time0 (count)			
N	24		
Mean (SD)	1.5 (0.9)		
Median (IQR)	1.0 (1.0 - 2.0)		
Min ; Max	1 ; 4		
Platelets from time0 until 24 hours after time0 (count)			
N	28		
Mean (SD)	1.5 (0.8)		
Median (IQR)	1.0 (1.0 - 2.0)		
Min ; Max	1 ; 4		
Platelets overall* (count)			
N	36	11	47
Mean (SD)	1.9 (1.0)	1.4 (0.9)	1.8 (1.0)
Median (IQR)	2.0 (1.0 - 3.0)	1.0 (1.0 - 1.0)	1.0 (1.0 - 3.0)
Min ; Max	1 ; 4	1 ; 4	1 ; 4

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, PLT: platelet.

*Overall is measured in the period from delivery to stop of PPH.

Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses. Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - full analysis set

PS analysis set

NovoSeven®

Matched controls

Platelets from delivery to time0 (mL)

N	4	3.5
Mean (SD)	125.0 (0.0)	125.0 (0.0)
Median (IQR)	125.0 (125.0 - 125.0)	125.0 (125.0 - 125.0)
Min ; Max	125 ; 125	125 ; 125

Platelets from time0 until 24 hours after time0 (mL)

N	8	9.7
Mean (SD)	187.5 (94.5)	247.8 (74.0)
Median (IQR)	125.0 (125.0 - 250.0)	250.0 (125.0 - 375.0)
Min ; Max	125 ; 375	125 ; 375

Platelets overall* (mL)

N	10	10.3
Mean (SD)	187.5 (106.2)	258.1 (89.7)
Median (IQR)	125.0 (125.0 - 250.0)	250.0 (125.0 - 375.0)
Min ; Max	125 ; 375	125 ; 500

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, PLT: platelet.

*Overall is measured in the period from delivery to stop of PPH.

Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses. Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - full analysis set

Full analysis set			
	NovoSeven®	No NovoSeven®	Total
Platelets from delivery to time0 (mL)			
N	24		
Mean (SD)	187.5 (110.6)		
Median (IQR)	125.0 (125.0 - 250.0)		
Min ; Max	125 ; 500		
Platelets from time0 until 24 hours after time0 (mL)			
N	28		
Mean (SD)	187.5 (99.2)		
Median (IQR)	125.0 (125.0 - 250.0)		
Min ; Max	125 ; 500		
Platelets overall* (mL)			
N	36	11	47
Mean (SD)	243.1 (119.3)	170.5 (115.6)	226.1 (121.2)
Median (IQR)	250.0 (125.0 - 375.0)	125.0 (125.0 - 125.0)	125.0 (125.0 - 375.0)
Min ; Max	125 ; 500	125 ; 500	125 ; 500

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, PLT: platelet.

*Overall is measured in the period from delivery to stop of PPH.

Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses. Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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14.1.12 Concomitant medications - by concomitant use before time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	4	7	2	5
Oxytocin from delivery to time0 (count)				
N	4	7	2	3
Mean (SD)	1.8 (1.0)	1.9 (0.7)	3.5 (3.5)	3.0 (1.0)
Median (IQR)	1.5 (1.0 - 2.5)	2.0 (1.0 - 2.0)	3.5 (1.0 - 6.0)	3.0 (2.0 - 4.0)
Min ; Max	1 ; 3	1 ; 3	1 ; 6	2 ; 4
Oxytocin from time0 until 24 hours after time0 (count)				
N	3	4	0	2
Mean (SD)	1.3 (0.6)	1.0 (0.0)		1.0 (0.0)
Median (IQR)	1.0 (1.0 - 2.0)	1.0 (1.0 - 1.0)		1.0 (1.0 - 1.0)
Min ; Max	1 ; 2	1 ; 1		1 ; 1
Oxytocin overall* (count)				
N	4	7	2	3
Mean (SD)	2.3 (1.0)	2.1 (0.9)	3.5 (3.5)	3.3 (1.2)
Median (IQR)	2.5 (1.5 - 3.0)	2.0 (1.0 - 3.0)	3.5 (1.0 - 6.0)	4.0 (2.0 - 4.0)
Min ; Max	1 ; 3	1 ; 3	1 ; 6	2 ; 4
Other uterotonics from delivery to time0 (count)				
N	3	7	1	4
Mean (SD)	1.3 (0.6)	1.7 (0.5)	4.0 (NE)	1.3 (0.5)
Median (IQR)	1.0 (1.0 - 2.0)	2.0 (1.0 - 2.0)	4.0 (4.0 - 4.0)	1.0 (1.0 - 1.5)
Min ; Max	1 ; 2	1 ; 2	4 ; 4	1 ; 2

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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Concomitant medications - by concomitant use before time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Other uterotonics from time0 until 24 hours after time0 (count)				
N	4	2	1	2
Mean (SD)	1.5 (0.6)	1.0 (0.0)	2.0 (NE)	1.0 (0.0)
Median (IQR)	1.5 (1.0 - 2.0)	1.0 (1.0 - 1.0)	2.0 (2.0 - 2.0)	1.0 (1.0 - 1.0)
Min ; Max	1 ; 2	1 ; 1	2 ; 2	1 ; 1
Other uterotonics overall* (count)				
N	4	7	2	4
Mean (SD)	2.3 (0.5)	2.0 (0.8)	3.0 (1.4)	1.5 (0.6)
Median (IQR)	2.0 (2.0 - 2.5)	2.0 (1.0 - 3.0)	3.0 (2.0 - 4.0)	1.5 (1.0 - 2.0)
Min ; Max	2 ; 3	1 ; 3	2 ; 4	1 ; 2
Colloids from delivery to time0 (mL)				
N	3	6	1	4
Mean (SD)	1333.3 (763.8)	1166.7 (752.8)	2000.0 (NE)	875.0 (478.7)
Median (IQR)	1500.0 (500.0 - 2000.0)	1000.0 (500.0 - 1500.0)	2000.0 (2000.0 - 2000.0)	750.0 (500.0 - 1250.0)
Min ; Max	500 ; 2000	500 ; 2500	2000 ; 2000	500 ; 1500
Colloids from time0 until 24 hours after time0 (mL)				
N	0	2	0	3
Mean (SD)		500.0 (0.0)		666.7 (288.7)
Median (IQR)		500.0 (500.0 - 500.0)		500.0 (500.0 - 1000.0)
Min ; Max		500 ; 500		500 ; 1000

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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Concomitant medications - by concomitant use before time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Colloids overall* (mL)				
N	3	6	1	5
Mean (SD)	1333.3 (763.8)	1333.3 (683.1)	2000.0 (NE)	1100.0 (821.6)
Median (IQR)	1500.0 (500.0 - 2000.0)	1250.0 (1000.0 - 1500.0)	2000.0 (2000.0 - 2000.0)	1000.0 (500.0 - 1000.0)
Min ; Max	500 ; 2000	500 ; 2500	2000 ; 2000	500 ; 2500
Crystalloids from delivery to time0 (mL)				
N	4	7	1	3
Mean (SD)	1675.0 (1192.7)	1471.4 (631.7)	4500.0 (NE)	1500.0 (1322.9)
Median (IQR)	1500.0 (750.0 - 2600.0)	1500.0 (1000.0 - 2000.0)	4500.0 (4500.0 - 4500.0)	1000.0 (500.0 - 3000.0)
Min ; Max	500 ; 3200	600 ; 2500	4500 ; 4500	500 ; 3000
Crystalloids from time0 until 24 hours after time0 (mL)				
N	4	6	0	3
Mean (SD)	2225.0 (801.6)	1333.3 (605.5)		1433.3 (275.4)
Median (IQR)	2350.0 (1600.0 - 2850.0)	1000.0 (1000.0 - 1500.0)		1300.0 (1250.0 - 1750.0)
Min ; Max	1200 ; 3000	1000 ; 2500		1250 ; 1750
Crystalloids overall* (mL)				
N	4	7	1	4
Mean (SD)	2700.0 (1151.8)	2114.3 (1190.8)	4500.0 (NE)	1887.5 (1049.1)
Median (IQR)	2650.0 (1750.0 - 3650.0)	2000.0 (1000.0 - 3500.0)	4500.0 (4500.0 - 4500.0)	2025.0 (1150.0 - 2625.0)
Min ; Max	1500 ; 4000	600 ; 3700	4500 ; 4500	500 ; 3000

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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Concomitant medications - by concomitant use before time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Red blood cells from delivery to time0 (count)				
N	4	7	1	4
Mean (SD)	4.0 (1.4)	3.6 (3.0)	10.0 (NE)	4.5 (3.1)
Median (IQR)	4.5 (3.0 - 5.0)	2.0 (1.0 - 6.0)	10.0 (10.0 - 10.0)	4.5 (2.0 - 7.0)
Min ; Max	2 ; 5	1 ; 9	10 ; 10	1 ; 8
Red blood cells from time0 until 24 hours after time0 (count)				
N	3	5	2	5
Mean (SD)	7.3 (5.9)	8.2 (7.3)	6.0 (2.8)	6.4 (4.0)
Median (IQR)	5.0 (3.0 - 14.0)	7.0 (4.0 - 9.0)	6.0 (4.0 - 8.0)	6.0 (3.0 - 10.0)
Min ; Max	3 ; 14	1 ; 20	4 ; 8	2 ; 11
Red blood cells overall* (count)				
N	4	7	2	5
Mean (SD)	9.5 (7.0)	9.4 (9.2)	11.0 (4.2)	9.8 (5.1)
Median (IQR)	8.5 (5.0 - 14.0)	8.0 (2.0 - 11.0)	11.0 (8.0 - 14.0)	11.0 (11.0 - 12.0)
Min ; Max	2 ; 19	2 ; 29	8 ; 14	1 ; 14

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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Concomitant medications - by concomitant use before time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Red blood cells from delivery to time0 (mL)				
N	4	7	1	4
Mean (SD)	1100.0 (388.9)	982.1 (822.8)	2750.0 (NE)	1237.5 (855.0)
Median (IQR)	1237.5 (825.0 - 1375.0)	550.0 (275.0 - 1650.0)	2750.0 (2750.0 - 2750.0)	1237.5 (550.0 - 1925.0)
Min ; Max	550 ; 1375	275 ; 2475	2750 ; 2750	275 ; 2200
Red blood cells from time0 until 24 hours after time0 (mL)				
N	3	5	2	5
Mean (SD)	2016.7 (1611.4)	2255.0 (1996.4)	1650.0 (777.8)	1760.0 (1110.3)
Median (IQR)	1375.0 (825.0 - 3850.0)	1925.0 (1100.0 - 2475.0)	1650.0 (1100.0 - 2200.0)	1650.0 (825.0 - 2750.0)
Min ; Max	825 ; 3850	275 ; 5500	1100 ; 2200	550 ; 3025
Red blood cells overall* (mL)				
N	4	7	2	5
Mean (SD)	2612.5 (1938.1)	2592.9 (2539.6)	3025.0 (1166.7)	2695.0 (1394.1)
Median (IQR)	2337.5 (1375.0 - 3850.0)	2200.0 (550.0 - 3025.0)	3025.0 (2200.0 - 3850.0)	3025.0 (3025.0 - 3300.0)
Min ; Max	550 ; 5225	550 ; 7975	2200 ; 3850	275 ; 3850

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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Concomitant medications - by concomitant use before time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
FFP transfusion from delivery to time0 (count)				
N	4	5	1	4
Mean (SD)	3.0 (2.2)	4.4 (2.7)	9.0 (NE)	4.5 (3.9)
Median (IQR)	2.5 (1.5 - 4.5)	4.0 (3.0 - 4.0)	9.0 (9.0 - 9.0)	3.5 (2.0 - 7.0)
Min ; Max	1 ; 6	2 ; 9	9 ; 9	1 ; 10
FFP transfusion from time0 until 24 hours after time0 (count)				
N	4	6	2	5
Mean (SD)	6.0 (7.6)	7.3 (7.8)	4.5 (4.9)	4.6 (2.8)
Median (IQR)	3.0 (1.0 - 11.0)	5.0 (3.0 - 6.0)	4.5 (1.0 - 8.0)	4.0 (2.0 - 7.0)
Min ; Max	1 ; 17	2 ; 23	1 ; 8	2 ; 8
FFP transfusion overall* (count)				
N	4	7	2	5
Mean (SD)	8.5 (7.6)	9.4 (10.1)	9.0 (1.4)	8.0 (4.3)
Median (IQR)	6.5 (3.0 - 14.0)	6.0 (4.0 - 8.0)	9.0 (8.0 - 10.0)	8.0 (8.0 - 11.0)
Min ; Max	2 ; 19	4 ; 32	8 ; 10	1 ; 12

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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Concomitant medications - by concomitant use before time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
FFP transfusion from delivery to time0 (mL)				
N	4	5	1	4
Mean (SD)	840.0 (604.9)	1232.0 (756.5)	2520.0 (NE)	1260.0 (1084.4)
Median (IQR)	700.0 (420.0 - 1260.0)	1120.0 (840.0 - 1120.0)	2520.0 (2520.0 - 2520.0)	980.0 (560.0 - 1960.0)
Min ; Max	280 ; 1680	560 ; 2520	2520 ; 2520	280 ; 2800
FFP transfusion from time0 until 24 hours after time0 (mL)				
N	4	6	2	5
Mean (SD)	1680.0 (2120.1)	2053.3 (2195.2)	1260.0 (1385.9)	1288.0 (782.0)
Median (IQR)	840.0 (280.0 - 3080.0)	1400.0 (840.0 - 1680.0)	1260.0 (280.0 - 2240.0)	1120.0 (560.0 - 1960.0)
Min ; Max	280 ; 4760	560 ; 6440	280 ; 2240	560 ; 2240
FFP transfusion overall* (mL)				
N	4	7	2	5
Mean (SD)	2380.0 (2126.3)	2640.0 (2817.9)	2520.0 (396.0)	2240.0 (1204.3)
Median (IQR)	1820.0 (840.0 - 3920.0)	1680.0 (1120.0 - 2240.0)	2520.0 (2240.0 - 2800.0)	2240.0 (2240.0 - 3080.0)
Min ; Max	560 ; 5320	1120 ; 8960	2240 ; 2800	280 ; 3360

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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Concomitant medications - by concomitant use before time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Platelets from delivery to time0 (count)				
N	1	2	0	1
Mean (SD)	1.0 (NE)	1.0 (0.0)		1.0 (NE)
Median (IQR)	1.0 (1.0 - 1.0)	1.0 (1.0 - 1.0)		1.0 (1.0 - 1.0)
Min ; Max	1 ; 1	1 ; 1		1 ; 1
Platelets from time0 until 24 hours after time0 (count)				
N	2	2	1	3
Mean (SD)	2.0 (1.4)	1.5 (0.7)	1.0 (NE)	1.3 (0.6)
Median (IQR)	2.0 (1.0 - 3.0)	1.5 (1.0 - 2.0)	1.0 (1.0 - 1.0)	1.0 (1.0 - 2.0)
Min ; Max	1 ; 3	1 ; 2	1 ; 1	1 ; 2
Platelets overall* (count)				
N	3	3	0	4
Mean (SD)	1.7 (1.2)	1.7 (1.2)		1.3 (0.5)
Median (IQR)	1.0 (1.0 - 3.0)	1.0 (1.0 - 3.0)		1.0 (1.0 - 1.5)
Min ; Max	1 ; 3	1 ; 3		1 ; 2

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(≤) time0.

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	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Platelets from delivery to time0 (mL)				
N	1	2	0	1
Mean (SD)	125.0 (NE)	125.0 (0.0)		125.0 (NE)
Median (IQR)	125.0 (125.0 - 125.0)	125.0 (125.0 - 125.0)		125.0 (125.0 - 125.0)
Min ; Max	125 ; 125	125 ; 125		125 ; 125
Platelets from time0 until 24 hours after time0 (mL)				
N	2	2	1	3
Mean (SD)	250.0 (176.8)	187.5 (88.4)	125.0 (NE)	166.7 (72.2)
Median (IQR)	250.0 (125.0 - 375.0)	187.5 (125.0 - 250.0)	125.0 (125.0 - 125.0)	125.0 (125.0 - 250.0)
Min ; Max	125 ; 375	125 ; 250	125 ; 125	125 ; 250
Platelets overall* (mL)				
N	3	3	0	4
Mean (SD)	208.3 (144.3)	208.3 (144.3)		156.3 (62.5)
Median (IQR)	125.0 (125.0 - 375.0)	125.0 (125.0 - 375.0)		125.0 (125.0 - 187.5)
Min ; Max	125 ; 375	125 ; 375		125 ; 250

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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14.1.13 Concomitant medications - by concomitant use after time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	1	2	2	13
Oxytocin from delivery to time0 (count)				
N	0	1	2	13
Mean (SD)		1.0 (NE)	2.5 (0.7)	2.3 (1.4)
Median (IQR)		1.0 (1.0 - 1.0)	2.5 (2.0 - 3.0)	2.0 (1.0 - 3.0)
Min ; Max		1 ; 1	2 ; 3	1 ; 6
Oxytocin from time0 until 24 hours after time0 (count)				
N	1	0	2	6
Mean (SD)	1.0 (NE)		1.0 (0.0)	1.2 (0.4)
Median (IQR)	1.0 (1.0 - 1.0)		1.0 (1.0 - 1.0)	1.0 (1.0 - 1.0)
Min ; Max	1 ; 1		1 ; 1	1 ; 2
Oxytocin overall* (count)				
N	0	1	2	13
Mean (SD)		1.0 (NE)	3.0 (0.0)	2.6 (1.4)
Median (IQR)		1.0 (1.0 - 1.0)	3.0 (3.0 - 3.0)	2.0 (2.0 - 3.0)
Min ; Max		1 ; 1	3 ; 3	1 ; 6
Other uterotonics from delivery to time0 (count)				
N	1	1	1	12
Mean (SD)	2.0 (NE)	1.0 (NE)	2.0 (NE)	1.7 (0.9)
Median (IQR)	2.0 (2.0 - 2.0)	1.0 (1.0 - 1.0)	2.0 (2.0 - 2.0)	1.5 (1.0 - 2.0)
Min ; Max	2 ; 2	1 ; 1	2 ; 2	1 ; 4

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Other uterotonics from time0 until 24 hours after time0 (count)				
N	1	1	2	5
Mean (SD)	1.0 (NE)	2.0 (NE)	1.5 (0.7)	1.2 (0.4)
Median (IQR)	1.0 (1.0 - 1.0)	2.0 (2.0 - 2.0)	1.5 (1.0 - 2.0)	1.0 (1.0 - 1.0)
Min ; Max	1 ; 1	2 ; 2	1 ; 2	1 ; 2
Other uterotonics overall* (count)				
N	1	2	2	12
Mean (SD)	2.0 (NE)	1.5 (0.7)	2.5 (0.7)	2.1 (0.9)
Median (IQR)	2.0 (2.0 - 2.0)	1.5 (1.0 - 2.0)	2.5 (2.0 - 3.0)	2.0 (1.5 - 2.5)
Min ; Max	2 ; 2	1 ; 2	2 ; 3	1 ; 4
Colloids from delivery to time0 (mL)				
N	0	1	2	11
Mean (SD)		500.0 (NE)	1250.0 (1060.7)	1227.3 (646.7)
Median (IQR)		500.0 (500.0 - 500.0)	1250.0 (500.0 - 2000.0)	1000.0 (500.0 - 1500.0)
Min ; Max		500 ; 500	500 ; 2000	500 ; 2500
Colloids from time0 until 24 hours after time0 (mL)				
N	1	1	1	2
Mean (SD)	500.0 (NE)	500.0 (NE)	500.0 (NE)	750.0 (353.6)
Median (IQR)	500.0 (500.0 - 500.0)	500.0 (500.0 - 500.0)	500.0 (500.0 - 500.0)	750.0 (500.0 - 1000.0)
Min ; Max	500 ; 500	500 ; 500	500 ; 500	500 ; 1000

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Colloids overall* (mL)				
N	1	1	2	11
Mean (SD)	500.0 (NE)	1000.0 (NE)	1500.0 (707.1)	1363.6 (744.7)
Median (IQR)	500.0 (500.0 - 500.0)	1000.0 (1000.0 - 1000.0)	1500.0 (1000.0 - 2000.0)	1500.0 (500.0 - 2000.0)
Min ; Max	500 ; 500	1000 ; 1000	1000 ; 2000	500 ; 2500
Crystalloids from delivery to time0 (mL)				
N	0	0	2	13
Mean (SD)			2200.0 (1414.2)	1661.5 (1153.6)
Median (IQR)			2200.0 (1200.0 - 3200.0)	1500.0 (1000.0 - 2000.0)
Min ; Max			1200 ; 3200	500 ; 4500
Crystalloids from time0 until 24 hours after time0 (mL)				
N	1	0	2	10
Mean (SD)	1750.0 (NE)		1850.0 (919.2)	1575.0 (744.3)
Median (IQR)	1750.0 (1750.0 - 1750.0)		1850.0 (1200.0 - 2500.0)	1275.0 (1000.0 - 2000.0)
Min ; Max	1750 ; 1750		1200 ; 2500	1000 ; 3000
Crystalloids overall* (mL)				
N	1	0	2	13
Mean (SD)	500.0 (NE)		3500.0 (282.8)	2319.2 (1154.3)
Median (IQR)	500.0 (500.0 - 500.0)		3500.0 (3300.0 - 3700.0)	2000.0 (1500.0 - 3000.0)
Min ; Max	500 ; 500		3300 ; 3700	600 ; 4500

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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Concomitant medications - by concomitant use after time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Red blood cells from delivery to time0 (count)				
N	0	1	2	13
Mean (SD)		3.0 (NE)	3.0 (1.4)	4.6 (3.1)
Median (IQR)		3.0 (3.0 - 3.0)	3.0 (2.0 - 4.0)	5.0 (2.0 - 6.0)
Min ; Max		3 ; 3	2 ; 4	1 ; 10
Red blood cells from time0 until 24 hours after time0 (count)				
N	1	2	2	10
Mean (SD)	2.0 (NE)	9.5 (2.1)	7.0 (2.8)	7.2 (5.9)
Median (IQR)	2.0 (2.0 - 2.0)	9.5 (8.0 - 11.0)	7.0 (5.0 - 9.0)	5.0 (3.0 - 10.0)
Min ; Max	2 ; 2	8 ; 11	5 ; 9	1 ; 20
Red blood cells overall* (count)				
N	1	2	2	13
Mean (SD)	1.0 (NE)	11.0 (4.2)	10.0 (1.4)	10.2 (7.5)
Median (IQR)	1.0 (1.0 - 1.0)	11.0 (8.0 - 14.0)	10.0 (9.0 - 11.0)	8.0 (6.0 - 12.0)
Min ; Max	1 ; 1	8 ; 14	9 ; 11	2 ; 29

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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Concomitant medications - by concomitant use after time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Red blood cells from delivery to time0 (mL)				
N	0	1	2	13
Mean (SD)		825.0 (NE)	825.0 (388.9)	1269.2 (859.0)
Median (IQR)		825.0 (825.0 - 825.0)	825.0 (550.0 - 1100.0)	1375.0 (550.0 - 1650.0)
Min ; Max		825 ; 825	550 ; 1100	275 ; 2750
Red blood cells from time0 until 24 hours after time0 (mL)				
N	1	2	2	10
Mean (SD)	550.0 (NE)	2612.5 (583.4)	1925.0 (777.8)	1980.0 (1623.3)
Median (IQR)	550.0 (550.0 - 550.0)	2612.5 (2200.0 - 3025.0)	1925.0 (1375.0 - 2475.0)	1375.0 (825.0 - 2750.0)
Min ; Max	550 ; 550	2200 ; 3025	1375 ; 2475	275 ; 5500
Red blood cells overall* (mL)				
N	1	2	2	13
Mean (SD)	275.0 (NE)	3025.0 (1166.7)	2750.0 (388.9)	2792.3 (2075.7)
Median (IQR)	275.0 (275.0 - 275.0)	3025.0 (2200.0 - 3850.0)	2750.0 (2475.0 - 3025.0)	2200.0 (1650.0 - 3300.0)
Min ; Max	275 ; 275	2200 ; 3850	2475 ; 3025	550 ; 7975

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

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Concomitant medications - by concomitant use after time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
FFP transfusion from delivery to time0 (count)				
N	0	1	2	11
Mean (SD)		3.0 (NE)	4.0 (2.8)	4.5 (3.3)
Median (IQR)		3.0 (3.0 - 3.0)	4.0 (2.0 - 6.0)	4.0 (2.0 - 9.0)
Min ; Max		3 ; 3	2 ; 6	1 ; 10
FFP transfusion from time0 until 24 hours after time0 (count)				
N	1	2	2	12
Mean (SD)	2.0 (NE)	8.0 (0.0)	5.5 (0.7)	5.9 (7.0)
Median (IQR)	2.0 (2.0 - 2.0)	8.0 (8.0 - 8.0)	5.5 (5.0 - 6.0)	3.5 (1.5 - 6.5)
Min ; Max	2 ; 2	8 ; 8	5 ; 6	1 ; 23
FFP transfusion overall* (count)				
N	1	2	2	13
Mean (SD)	1.0 (NE)	9.5 (2.1)	8.5 (0.7)	9.3 (8.1)
Median (IQR)	1.0 (1.0 - 1.0)	9.5 (8.0 - 11.0)	8.5 (8.0 - 9.0)	7.0 (4.0 - 10.0)
Min ; Max	1 ; 1	8 ; 11	8 ; 9	2 ; 32

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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Concomitant medications - by concomitant use after time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
FFP transfusion from delivery to time0 (mL)				
N	0	1	2	11
Mean (SD)		840.0 (NE)	1120.0 (792.0)	1272.7 (914.7)
Median (IQR)		840.0 (840.0 - 840.0)	1120.0 (560.0 - 1680.0)	1120.0 (560.0 - 2520.0)
Min ; Max		840 ; 840	560 ; 1680	280 ; 2800
FFP transfusion from time0 until 24 hours after time0 (mL)				
N	1	2	2	12
Mean (SD)	560.0 (NE)	2240.0 (0.0)	1540.0 (198.0)	1656.7 (1952.6)
Median (IQR)	560.0 (560.0 - 560.0)	2240.0 (2240.0 - 2240.0)	1540.0 (1400.0 - 1680.0)	980.0 (420.0 - 1820.0)
Min ; Max	560 ; 560	2240 ; 2240	1400 ; 1680	280 ; 6440
FFP transfusion overall* (mL)				
N	1	2	2	13
Mean (SD)	280.0 (NE)	2660.0 (594.0)	2380.0 (198.0)	2606.2 (2275.8)
Median (IQR)	280.0 (280.0 - 280.0)	2660.0 (2240.0 - 3080.0)	2380.0 (2240.0 - 2520.0)	1960.0 (1120.0 - 2800.0)
Min ; Max	280 ; 280	2240 ; 3080	2240 ; 2520	560 ; 8960

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

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Concomitant medications - by concomitant use after time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Platelets from delivery to time0 (count)				
N	0	0	0	4
Mean (SD)				1.0 (0.0)
Median (IQR)				1.0 (1.0 - 1.0)
Min ; Max				1 ; 1
Platelets from time0 until 24 hours after time0 (count)				
N	0	2	2	4
Mean (SD)		1.5 (0.7)	1.0 (0.0)	1.8 (1.0)
Median (IQR)		1.5 (1.0 - 2.0)	1.0 (1.0 - 1.0)	1.5 (1.0 - 2.5)
Min ; Max		1 ; 2	1 ; 1	1 ; 3
Platelets overall* (count)				
N	0	1	2	7
Mean (SD)		2.0 (NE)	1.0 (0.0)	1.6 (1.0)
Median (IQR)		2.0 (2.0 - 2.0)	1.0 (1.0 - 1.0)	1.0 (1.0 - 3.0)
Min ; Max		2 ; 2	1 ; 1	1 ; 3

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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Concomitant medications - by concomitant use after time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Platelets from delivery to time0 (mL)				
N	0	0	0	4
Mean (SD)				125.0 (0.0)
Median (IQR)				125.0 (125.0 - 125.0)
Min ; Max				125 ; 125
Platelets from time0 until 24 hours after time0 (mL)				
N	0	2	2	4
Mean (SD)		187.5 (88.4)	125.0 (0.0)	218.8 (119.7)
Median (IQR)		187.5 (125.0 - 250.0)	125.0 (125.0 - 125.0)	187.5 (125.0 - 312.5)
Min ; Max		125 ; 250	125 ; 125	125 ; 375
Platelets overall* (mL)				
N	0	1	2	7
Mean (SD)		250.0 (NE)	125.0 (0.0)	196.4 (122.0)
Median (IQR)		250.0 (250.0 - 250.0)	125.0 (125.0 - 125.0)	125.0 (125.0 - 375.0)
Min ; Max		250 ; 250	125 ; 125	125 ; 375

PS: Propensity score, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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14.1.14 Concomitant medications - by concomitant use before time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	4	17	1	21
Number of weighted patients, N	1.6	6.7	1.0	8.8
Oxytocin from delivery to time0 (count)				
N	1.1	5.1	1.0	8.0
Mean (SD)	1.8 (0.6)	2.2 (0.8)	6.0 (NE)	1.8 (0.5)
Median (IQR)	2.0 (1.0 - 3.0)	2.0 (1.0 - 3.0)	6.0 (6.0 - 6.0)	2.0 (1.0 - 2.0)
Min ; Max	1 ; 3	1 ; 4	6 ; 6	1 ; 3
Oxytocin from time0 until 24 hours after time0 (count)				
N	1.3	2.3	0	4.8
Mean (SD)	2.2 (1.2)	1.0 (0.0)		1.7 (0.3)
Median (IQR)	1.0 (1.0 - 4.0)	1.0 (1.0 - 1.0)		2.0 (1.0 - 2.0)
Min ; Max	1 ; 4	1 ; 1		1 ; 2
Oxytocin overall* (count)				
N	1.6	5.3	1.0	8.3
Mean (SD)	1.9 (0.5)	2.8 (1.4)	6.0 (NE)	2.5 (0.8)
Median (IQR)	2.0 (1.0 - 2.0)	2.0 (1.0 - 5.0)	6.0 (6.0 - 6.0)	3.0 (1.0 - 4.0)
Min ; Max	1 ; 3	1 ; 6	6 ; 6	1 ; 4

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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Concomitant medications - by concomitant use before time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Other uterotonics from delivery to time0 (count)				
N	1.6	5.3	1.0	4.0
Mean (SD)	1.7 (0.6)	1.9 (0.6)	4.0 (NE)	1.1 (0.2)
Median (IQR)	2.0 (1.0 - 2.0)	2.0 (1.0 - 2.0)	4.0 (4.0 - 4.0)	1.0 (1.0 - 1.0)
Min ; Max	1 ; 3	1 ; 4	4 ; 4	1 ; 2
Other uterotonics from time0 until 24 hours after time0 (count)				
N	1.3	2.5	0	3.0
Mean (SD)	1.4 (0.4)	1.2 (0.3)		1.6 (0.5)
Median (IQR)	1.0 (1.0 - 2.0)	1.0 (1.0 - 1.0)		1.0 (1.0 - 2.0)
Min ; Max	1 ; 2	1 ; 2		1 ; 3
Other uterotonics overall* (count)				
N	1.6	5.6	1.0	5.3
Mean (SD)	2.5 (0.4)	2.2 (0.5)	4.0 (NE)	1.7 (0.5)
Median (IQR)	3.0 (2.0 - 3.0)	2.0 (2.0 - 2.0)	4.0 (4.0 - 4.0)	2.0 (1.0 - 2.0)
Min ; Max	2 ; 3	1 ; 4	4 ; 4	1 ; 4
Colloids from delivery to time0 (mL)				
N	1.6	5.4	1.0	8.0
Mean (SD)	500.0 (0.0)	1253.8 (477.2)	500.0 (NE)	1328.1 (450.6)
Median (IQR)	500.0 (500.0 - 500.0)	1500.0 (500.0 - 2000.0)	500.0 (500.0 - 500.0)	1500.0 (750.0 - 1750.0)
Min ; Max	500 ; 500	500 ; 2000	500 ; 500	500 ; 2500
Colloids from time0 until 24 hours after time0 (mL)				
N	0.3	3.3	1.0	4.4
Mean (SD)	500.0 (NE)	846.2 (366.9)	1500.0 (NE)	962.3 (397.1)
Median (IQR)	500.0 (500.0 - 500.0)	500.0 (500.0 - 1500.0)	1500.0 (1500.0 - 1500.0)	500.0 (500.0 - 1500.0)
Min ; Max	500 ; 500	500 ; 1500	1500 ; 1500	500 ; 2500

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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Concomitant medications - by concomitant use before time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Colloids overall* (mL)				
N	1.6	5.7	1.0	8.5
Mean (SD)	578.9 (132.5)	1860.3 (694.3)	2000.0 (NE)	1764.7 (651.8)
Median (IQR)	500.0 (500.0 - 500.0)	2000.0 (1000.0 - 2500.0)	2000.0 (2000.0 - 2000.0)	1500.0 (1000.0 - 2500.0)
Min ; Max	500 ; 1000	500 ; 3500	2000 ; 2000	500 ; 4000
Crystalloids from delivery to time0 (mL)				
N	1.6	5.6	1.0	8.8
Mean (SD)	2100.0 (519.6)	2044.8 (847.7)	2500.0 (NE)	2160.5 (1019.8)
Median (IQR)	2400.0 (2200.0 - 2400.0)	1500.0 (1000.0 - 3400.0)	2500.0 (2500.0 - 2500.0)	2500.0 (750.0 - 3000.0)
Min ; Max	500 ; 2700	500 ; 4100	2500 ; 2500	500 ; 7000
Crystalloids from time0 until 24 hours after time0 (mL)				
N	1.6	5.5	1.0	7.0
Mean (SD)	2200.0 (1340.4)	1584.1 (676.3)	2000.0 (NE)	2283.3 (989.1)
Median (IQR)	1600.0 (1000.0 - 4800.0)	1500.0 (1000.0 - 2050.0)	2000.0 (2000.0 - 2000.0)	2000.0 (1000.0 - 3000.0)
Min ; Max	100 ; 4800	300 ; 4000	2000 ; 2000	500 ; 8000
Crystalloids overall* (mL)				
N	1.6	6.1	1.0	8.8
Mean (SD)	2784.2 (884.5)	3173.3 (922.1)	4500.0 (NE)	3686.2 (1187.3)
Median (IQR)	2800.0 (2500.0 - 4200.0)	3500.0 (2000.0 - 4400.0)	4500.0 (4500.0 - 4500.0)	3100.0 (2500.0 - 5500.0)
Min ; Max	500 ; 4200	500 ; 5250	4500 ; 4500	750 ; 7000

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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Concomitant medications - by concomitant use before time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Red blood cells from delivery to time0 (count)				
N	1.3	5.2	1.0	6.8
Mean (SD)	3.3 (1.3)	4.9 (1.5)	3.0 (NE)	4.5 (2.0)
Median (IQR)	3.0 (2.0 - 5.0)	5.0 (2.0 - 6.0)	3.0 (3.0 - 3.0)	4.0 (2.0 - 5.0)
Min ; Max	1 ; 5	2 ; 8	3 ; 3	2 ; 10
Red blood cells from time0 until 24 hours after time0 (count)				
N	1.6	5.4	1.0	8.4
Mean (SD)	3.9 (2.1)	6.9 (3.9)	11.0 (NE)	9.2 (3.2)
Median (IQR)	2.0 (1.0 - 8.0)	6.0 (3.0 - 8.0)	11.0 (11.0 - 11.0)	10.0 (5.0 - 14.0)
Min ; Max	1 ; 8	1 ; 23	11 ; 11	2 ; 17
Red blood cells overall* (count)				
N	1.6	6.4	1.0	8.5
Mean (SD)	6.2 (2.7)	10.2 (4.5)	14.0 (NE)	11.8 (4.7)
Median (IQR)	6.0 (4.0 - 11.0)	12.0 (4.0 - 12.0)	14.0 (14.0 - 14.0)	10.0 (7.0 - 16.0)
Min ; Max	1 ; 11	2 ; 29	14 ; 14	2 ; 24

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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Concomitant medications - by concomitant use before time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Red blood cells from delivery to time0 (mL)				
N	1.3	5.2	1.0	6.8
Mean (SD)	893.8 (350.6)	1348.4 (425.6)	825.0 (NE)	1225.6 (537.5)
Median (IQR)	825.0 (550.0 - 1375.0)	1375.0 (550.0 - 1650.0)	825.0 (825.0 - 825.0)	1100.0 (550.0 - 1375.0)
Min ; Max	275 ; 1375	550 ; 2200	825 ; 825	550 ; 2750
Red blood cells from time0 until 24 hours after time0 (mL)				
N	1.6	5.4	1.0	8.4
Mean (SD)	1071.1 (590.1)	1908.1 (1059.5)	3025.0 (NE)	2540.3 (890.4)
Median (IQR)	550.0 (275.0 - 2200.0)	1650.0 (825.0 - 2200.0)	3025.0 (3025.0 - 3025.0)	2750.0 (1375.0 - 3850.0)
Min ; Max	275 ; 2200	275 ; 6325	3025 ; 3025	550 ; 4675
Red blood cells overall* (mL)				
N	1.6	6.4	1.0	8.5
Mean (SD)	1707.9 (740.7)	2803.6 (1247.5)	3850.0 (NE)	3254.2 (1292.2)
Median (IQR)	1650.0 (1100.0 - 3025.0)	3300.0 (1100.0 - 3300.0)	3850.0 (3850.0 - 3850.0)	2750.0 (1925.0 - 4400.0)
Min ; Max	275 ; 3025	550 ; 7975	3850 ; 3850	550 ; 6600

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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Concomitant medications - by concomitant use before time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
FFP transfusion from delivery to time0 (count)				
N	1.6	4.9	1.0	6.2
Mean (SD)	2.2 (1.0)	4.5 (1.5)	3.0 (NE)	4.3 (2.1)
Median (IQR)	2.0 (1.0 - 4.0)	4.0 (3.0 - 6.0)	3.0 (3.0 - 3.0)	4.0 (3.0 - 4.0)
Min ; Max	1 ; 4	1 ; 8	3 ; 3	1 ; 10
FFP transfusion from time0 until 24 hours after time0 (count)				
N	0.8	4.6	1.0	7.9
Mean (SD)	5.7 (0.8)	6.5 (4.7)	7.0 (NE)	7.8 (2.3)
Median (IQR)	5.0 (5.0 - 7.0)	5.0 (2.0 - 6.0)	7.0 (7.0 - 7.0)	8.0 (6.0 - 9.0)
Min ; Max	5 ; 7	1 ; 26	7 ; 7	1 ; 14
FFP transfusion overall* (count)				
N	1.6	5.7	1.0	8.4
Mean (SD)	4.4 (1.1)	9.8 (5.2)	10.0 (NE)	10.2 (3.9)
Median (IQR)	4.0 (4.0 - 6.0)	9.0 (5.5 - 12.0)	10.0 (10.0 - 10.0)	11.0 (5.0 - 13.0)
Min ; Max	2 ; 6	2 ; 32	10 ; 10	2 ; 23

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by concomitant use before time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
FFP transfusion from delivery to time0 (mL)				
N	1.6	4.9	1.0	6.2
Mean (SD)	604.2 (266.1)	1262.4 (431.7)	840.0 (NE)	1210.8 (597.4)
Median (IQR)	560.0 (280.0 - 1120.0)	1120.0 (840.0 - 1680.0)	840.0 (840.0 - 840.0)	1120.0 (840.0 - 1120.0)
Min ; Max	280 ; 1120	280 ; 2240	840 ; 840	280 ; 2800
FFP transfusion from time0 until 24 hours after time0 (mL)				
N	0.8	4.6	1.0	7.9
Mean (SD)	1586.7 (228.6)	1827.6 (1311.4)	1960.0 (NE)	2172.2 (633.4)
Median (IQR)	1400.0 (1400.0 - 1960.0)	1400.0 (560.0 - 1680.0)	1960.0 (1960.0 - 1960.0)	2240.0 (1680.0 - 2520.0)
Min ; Max	1400 ; 1960	280 ; 7280	1960 ; 1960	280 ; 3920
FFP transfusion overall* (mL)				
N	1.6	5.7	1.0	8.4
Mean (SD)	1223.2 (296.7)	2746.5 (1469.9)	2800.0 (NE)	2855.4 (1081.6)
Median (IQR)	1120.0 (1120.0 - 1680.0)	2520.0 (1540.0 - 3360.0)	2800.0 (2800.0 - 2800.0)	3080.0 (1400.0 - 3640.0)
Min ; Max	560 ; 1680	560 ; 8960	2800 ; 2800	560 ; 6440

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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Concomitant medications - by concomitant use before time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Platelets from delivery to time0 (count)				
N	0.5	1.0	0	2.0
Mean (SD)	1.0 (NE)	1.0 (NE)		1.0 (0.0)
Median (IQR)	1.0 (1.0 - 1.0)	1.0 (1.0 - 1.0)		1.0 (1.0 - 1.0)
Min ; Max	1 ; 1	1 ; 1		1 ; 1
Platelets from time0 until 24 hours after time0 (count)				
N	0.8	3.1	0	5.8
Mean (SD)	2.3 (0.8)	2.1 (0.6)		1.9 (0.6)
Median (IQR)	3.0 (1.0 - 3.0)	2.0 (1.0 - 3.0)		2.0 (1.0 - 2.0)
Min ; Max	1 ; 3	1 ; 3		1 ; 3
Platelets overall* (count)				
N	0.8	3.8	0	5.8
Mean (SD)	3.0 (1.2)	1.9 (0.7)		2.0 (0.7)
Median (IQR)	4.0 (1.0 - 4.0)	2.0 (1.0 - 3.0)		2.0 (1.0 - 3.0)
Min ; Max	1 ; 4	1 ; 3		1 ; 3

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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Concomitant medications - by concomitant use before time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Platelets from delivery to time0 (mL)				
N	0.5	1.0	0	2.0
Mean (SD)	125.0 (NE)	125.0 (NE)		125.0 (0.0)
Median (IQR)	125.0 (125.0 - 125.0)	125.0 (125.0 - 125.0)		125.0 (125.0 - 125.0)
Min ; Max	125 ; 125	125 ; 125		125 ; 125
Platelets from time0 until 24 hours after time0 (mL)				
N	0.8	3.1	0	5.8
Mean (SD)	291.7 (102.1)	266.9 (81.1)		232.1 (70.9)
Median (IQR)	375.0 (125.0 - 375.0)	250.0 (125.0 - 375.0)		250.0 (125.0 - 250.0)
Min ; Max	125 ; 375	125 ; 375		125 ; 375
Platelets overall* (mL)				
N	0.8	3.8	0	5.8
Mean (SD)	375.0 (153.1)	241.7 (91.8)		253.6 (82.2)
Median (IQR)	500.0 (125.0 - 500.0)	250.0 (125.0 - 375.0)		250.0 (125.0 - 375.0)
Min ; Max	125 ; 500	125 ; 375		125 ; 375

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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14.1.15 Concomitant medications - by concomitant use after time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	5	12	7	19
Number of weighted patients, N	1.8	6.2	1.8	8.3
Oxytocin from delivery to time0 (count)				
N	1.5	5.9	0.8	6.9
Mean (SD)	2.2 (1.0)	2.0 (0.6)	1.3 (0.3)	2.5 (1.2)
Median (IQR)	1.5 (1.0 - 4.0)	2.0 (1.0 - 3.0)	1.0 (1.0 - 2.0)	2.0 (1.0 - 3.0)
Min ; Max	1 ; 4	1 ; 3	1 ; 2	1 ; 6
Oxytocin from time0 until 24 hours after time0 (count)				
N	1.0	2.8	0.3	4.3
Mean (SD)	1.3 (0.3)	1.9 (0.2)	1.0 (NE)	1.5 (0.6)
Median (IQR)	1.0 (1.0 - 1.5)	2.0 (2.0 - 2.0)	1.0 (1.0 - 1.0)	1.0 (1.0 - 2.0)
Min ; Max	1 ; 2	1 ; 2	1 ; 1	1 ; 4
Oxytocin overall* (count)				
N	1.5	6.2	1.1	7.4
Mean (SD)	2.8 (1.2)	2.7 (0.9)	1.2 (0.3)	3.0 (1.4)
Median (IQR)	2.5 (1.0 - 5.0)	3.0 (2.0 - 4.0)	1.0 (1.0 - 1.0)	2.0 (1.0 - 6.0)
Min ; Max	1 ; 5	1 ; 4	1 ; 2	1 ; 6

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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Concomitant medications - by concomitant use after time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Other uterotonics from delivery to time0 (count)				
N	1.0	3.4	1.8	5.7
Mean (SD)	2.8 (0.9)	1.0 (0.0)	1.9 (0.4)	2.0 (0.9)
Median (IQR)	3.0 (1.5 - 4.0)	1.0 (1.0 - 1.0)	2.0 (1.0 - 2.0)	2.0 (1.0 - 2.0)
Min ; Max	1 ; 4	1 ; 1	1 ; 3	1 ; 4
Other uterotonics from time0 until 24 hours after time0 (count)				
N	0.5	2.5	0.8	3.0
Mean (SD)	2.5 (0.4)	1.4 (0.4)	1.3 (0.3)	1.3 (0.3)
Median (IQR)	2.5 (2.0 - 3.0)	1.0 (1.0 - 2.0)	1.0 (1.0 - 2.0)	1.0 (1.0 - 1.5)
Min ; Max	2 ; 3	1 ; 3	1 ; 2	1 ; 2
Other uterotonics overall* (count)				
N	1.3	4.2	1.8	6.2
Mean (SD)	3.2 (0.6)	1.5 (0.3)	2.3 (0.4)	2.4 (0.6)
Median (IQR)	4.0 (2.0 - 4.0)	2.0 (1.0 - 2.0)	2.0 (2.0 - 3.0)	2.0 (2.0 - 3.0)
Min ; Max	2 ; 4	1 ; 2	1 ; 3	1 ; 4
Colloids from delivery to time0 (mL)				
N	1.5	5.9	1.3	7.3
Mean (SD)	1500.0 (288.7)	1309.9 (578.7)	687.5 (225.3)	1074.7 (454.9)
Median (IQR)	1500.0 (1000.0 - 2000.0)	1000.0 (500.0 - 2000.0)	500.0 (500.0 - 500.0)	500.0 (500.0 - 1500.0)
Min ; Max	1000 ; 2000	500 ; 2500	500 ; 1500	500 ; 2000
Colloids from time0 until 24 hours after time0 (mL)				
N	0.3	2.8	0.8	5.1
Mean (SD)	500.0 (NE)	897.1 (392.4)	666.7 (144.3)	1073.8 (445.3)
Median (IQR)	500.0 (500.0 - 500.0)	500.0 (500.0 - 1500.0)	500.0 (500.0 - 1000.0)	1000.0 (500.0 - 1500.0)
Min ; Max	500 ; 500	500 ; 1500	500 ; 1000	500 ; 2500

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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Concomitant medications - by concomitant use after time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Colloids overall* (mL)				
N	1.5	6.2	1.6	7.5
Mean (SD)	1583.3 (243.0)	1668.9 (561.6)	894.7 (403.9)	1916.7 (828.7)
Median (IQR)	1500.0 (1500.0 - 2000.0)	2000.0 (1000.0 - 2500.0)	500.0 (500.0 - 1000.0)	2000.0 (500.0 - 3000.0)
Min ; Max	1000 ; 2000	500 ; 2500	500 ; 2500	500 ; 4000
Crystalloids from delivery to time0 (mL)				
N	1.8	6.2	1.1	7.9
Mean (SD)	2014.3 (647.5)	2345.3 (947.8)	1607.7 (414.6)	2073.7 (1020.8)
Median (IQR)	1800.0 (1500.0 - 3400.0)	2500.0 (750.0 - 3100.0)	1500.0 (1000.0 - 2600.0)	2200.0 (1000.0 - 2500.0)
Min ; Max	500 ; 3400	500 ; 4100	1000 ; 2600	500 ; 7000
Crystalloids from time0 until 24 hours after time0 (mL)				
N	1.8	4.9	1.0	7.4
Mean (SD)	2557.1 (1559.5)	1900.0 (956.7)	2450.0 (759.9)	1875.8 (728.0)
Median (IQR)	1200.0 (1000.0 - 2850.0)	2000.0 (1000.0 - 3000.0)	2400.0 (1150.0 - 3750.0)	1600.0 (1100.0 - 2050.0)
Min ; Max	1000 ; 8000	300 ; 4000	1000 ; 4000	100 ; 4800
Crystalloids overall* (mL)				
N	1.8	6.2	1.6	7.9
Mean (SD)	3400.0 (813.7)	3562.8 (1259.8)	2600.0 (696.4)	3591.1 (1119.0)
Median (IQR)	3000.0 (2500.0 - 5250.0)	3100.0 (2500.0 - 4400.0)	2600.0 (1500.0 - 4000.0)	4000.0 (2500.0 - 4500.0)
Min ; Max	2000 ; 5250	500 ; 6500	1000 ; 4500	500 ; 7000

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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Concomitant medications - by concomitant use after time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Red blood cells from delivery to time0 (count)				
N	1.3	4.9	1.1	7.0
Mean (SD)	4.0 (0.9)	5.1 (2.6)	2.5 (0.5)	4.3 (1.5)
Median (IQR)	4.0 (4.0 - 5.0)	4.0 (2.0 - 6.0)	2.0 (2.0 - 2.0)	4.0 (3.0 - 5.5)
Min ; Max	2 ; 5	2 ; 10	2 ; 4	1 ; 8
Red blood cells from time0 until 24 hours after time0 (count)				
N	1.8	5.8	1.6	7.3
Mean (SD)	6.4 (2.7)	8.5 (3.1)	7.4 (2.7)	8.3 (4.3)
Median (IQR)	4.0 (4.0 - 8.0)	7.0 (6.0 - 14.0)	6.0 (5.0 - 8.0)	6.0 (2.0 - 11.0)
Min ; Max	2 ; 15	2 ; 15	3 ; 18	1 ; 23
Red blood cells overall* (count)				
N	1.5	6.2	1.8	8.0
Mean (SD)	10.0 (3.2)	11.2 (4.9)	7.3 (2.7)	11.5 (5.1)
Median (IQR)	10.5 (8.0 - 13.0)	10.0 (8.0 - 12.0)	8.0 (3.0 - 8.0)	12.0 (6.0 - 14.0)
Min ; Max	2 ; 16	2 ; 24	2 ; 18	1 ; 29

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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Concomitant medications - by concomitant use after time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Red blood cells from delivery to time0 (mL)				
N	1.3	4.9	1.1	7.0
Mean (SD)	1100.0 (238.2)	1389.0 (720.9)	676.9 (139.3)	1188.4 (405.0)
Median (IQR)	1100.0 (1100.0 - 1375.0)	1100.0 (550.0 - 1650.0)	550.0 (550.0 - 550.0)	1100.0 (825.0 - 1512.5)
Min ; Max	550 ; 1375	550 ; 2750	550 ; 1100	275 ; 2200
Red blood cells from time0 until 24 hours after time0 (mL)				
N	1.8	5.8	1.6	7.3
Mean (SD)	1767.9 (739.5)	2329.6 (842.9)	2040.8 (743.5)	2279.0 (1173.0)
Median (IQR)	1100.0 (1100.0 - 2200.0)	1925.0 (1650.0 - 3850.0)	1650.0 (1375.0 - 2200.0)	1650.0 (550.0 - 3025.0)
Min ; Max	550 ; 4125	550 ; 4125	825 ; 4950	275 ; 6325
Red blood cells overall* (mL)				
N	1.5	6.2	1.8	8.0
Mean (SD)	2750.0 (891.1)	3088.2 (1335.1)	2012.5 (739.6)	3168.2 (1402.8)
Median (IQR)	2887.5 (2200.0 - 3575.0)	2750.0 (2200.0 - 3300.0)	2200.0 (825.0 - 2200.0)	3300.0 (1650.0 - 3850.0)
Min ; Max	550 ; 4400	550 ; 6600	550 ; 4950	275 ; 7975

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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Concomitant medications - by concomitant use after time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
FFP transfusion from delivery to time0 (count)				
N	1.3	4.6	1.1	6.8
Mean (SD)	3.0 (0.9)	5.0 (2.6)	2.8 (0.6)	3.8 (1.6)
Median (IQR)	3.0 (3.0 - 4.0)	4.0 (4.0 - 4.0)	3.0 (3.0 - 3.0)	3.0 (3.0 - 5.0)
Min ; Max	1 ; 4	1 ; 10	1 ; 4	1 ; 8
FFP transfusion from time0 until 24 hours after time0 (count)				
N	1.8	5.6	1.6	5.3
Mean (SD)	5.4 (1.7)	7.9 (2.8)	4.1 (2.1)	8.0 (4.2)
Median (IQR)	5.0 (3.0 - 6.0)	7.0 (5.0 - 10.0)	2.0 (1.0 - 8.0)	7.0 (5.0 - 8.0)
Min ; Max	3 ; 11	2 ; 14	1 ; 11	1 ; 26
FFP transfusion overall* (count)				
N	1.8	5.6	1.6	7.8
Mean (SD)	7.6 (1.9)	11.4 (4.9)	5.9 (1.6)	9.3 (4.8)
Median (IQR)	6.0 (5.0 - 10.0)	9.0 (8.0 - 13.0)	5.0 (4.0 - 8.0)	10.0 (5.0 - 12.0)
Min ; Max	4 ; 12	2 ; 23	2 ; 11	2 ; 32

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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Concomitant medications - by concomitant use after time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
FFP transfusion from delivery to time0 (mL)				
N	1.3	4.6	1.1	6.8
Mean (SD)	840.0 (242.5)	1400.0 (740.8)	775.4 (176.5)	1061.2 (460.5)
Median (IQR)	840.0 (840.0 - 1120.0)	1120.0 (1120.0 - 1120.0)	840.0 (840.0 - 840.0)	840.0 (840.0 - 1400.0)
Min ; Max	280 ; 1120	280 ; 2800	280 ; 1120	280 ; 2240
FFP transfusion from time0 until 24 hours after time0 (mL)				
N	1.8	5.6	1.6	5.3
Mean (SD)	1520.0 (473.3)	2202.4 (781.7)	1134.7 (601.6)	2244.4 (1167.4)
Median (IQR)	1400.0 (840.0 - 1680.0)	1960.0 (1400.0 - 2800.0)	560.0 (280.0 - 2240.0)	1960.0 (1400.0 - 2240.0)
Min ; Max	840 ; 3080	560 ; 3920	280 ; 3080	280 ; 7280
FFP transfusion overall* (mL)				
N	1.8	5.6	1.6	7.8
Mean (SD)	2120.0 (522.5)	3201.2 (1365.5)	1665.3 (444.1)	2595.3 (1357.1)
Median (IQR)	1680.0 (1400.0 - 2800.0)	2520.0 (2240.0 - 3640.0)	1400.0 (1120.0 - 2240.0)	2800.0 (1400.0 - 3360.0)
Min ; Max	1120 ; 3360	560 ; 6440	560 ; 3080	560 ; 8960

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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Concomitant medications - by concomitant use after time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Platelets from delivery to time0 (count)				
N	0	1.0	0	2.5
Mean (SD)		1.0 (NE)		1.0 (0.0)
Median (IQR)		1.0 (1.0 - 1.0)		1.0 (1.0 - 1.0)
Min ; Max		1 ; 1		1 ; 1
Platelets from time0 until 24 hours after time0 (count)				
N	0.8	4.5	1.1	3.3
Mean (SD)	1.7 (0.8)	2.4 (0.5)	1.5 (0.3)	1.6 (0.6)
Median (IQR)	1.0 (1.0 - 3.0)	2.0 (2.0 - 3.0)	1.0 (1.0 - 2.0)	1.0 (1.0 - 3.0)
Min ; Max	1 ; 3	2 ; 3	1 ; 2	1 ; 3
Platelets overall* (count)				
N	0.8	4.5	0.8	4.3
Mean (SD)	1.7 (0.8)	2.4 (0.8)	1.7 (0.3)	1.8 (0.8)
Median (IQR)	1.0 (1.0 - 3.0)	3.0 (2.0 - 3.0)	2.0 (1.0 - 2.0)	1.0 (1.0 - 2.0)
Min ; Max	1 ; 3	1 ; 3	1 ; 2	1 ; 4

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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Concomitant medications - by concomitant use after time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Platelets from delivery to time0 (mL)				
N	0	1.0	0	2.5
Mean (SD)		125.0 (NE)		125.0 (0.0)
Median (IQR)		125.0 (125.0 - 125.0)		125.0 (125.0 - 125.0)
Min ; Max		125 ; 125		125 ; 125
Platelets from time0 until 24 hours after time0 (mL)				
N	0.8	4.5	1.1	3.3
Mean (SD)	208.3 (102.1)	305.6 (58.9)	182.7 (37.4)	200.0 (79.1)
Median (IQR)	125.0 (125.0 - 375.0)	250.0 (250.0 - 375.0)	125.0 (125.0 - 250.0)	125.0 (125.0 - 375.0)
Min ; Max	125 ; 375	250 ; 375	125 ; 250	125 ; 375
Platelets overall* (mL)				
N	0.8	4.5	0.8	4.3
Mean (SD)	208.3 (102.1)	305.6 (98.6)	208.3 (36.1)	226.0 (95.5)
Median (IQR)	125.0 (125.0 - 375.0)	375.0 (250.0 - 375.0)	250.0 (125.0 - 250.0)	125.0 (125.0 - 250.0)
Min ; Max	125 ; 375	125 ; 375	125 ; 250	125 ; 500

PS: Propensity score, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours after(>) time0.

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14.1.16 Concomitant medications - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony
Number of patients	4	1	0	13
Tranexamic acid from delivery to time0, N (%)				
Yes	4 (100.0)	1 (100.0)	0	5 (38.5)
No	0	0	0	8 (61.5)
Tranexamic acid from time0 until 24 hours after time0, N (%)				
Yes	0	0	0	3 (23.1)
No	4 (100.0)	1 (100.0)	0	10 (76.9)
Tranexamic acid overall*, N (%)				
Yes	4 (100.0)	1 (100.0)	0	8 (61.5)
No	0	0	0	5 (38.5)
Fibrinogen from delivery to time0, N (%)				
Yes	1 (25.0)	1 (100.0)	0	4 (30.8)
No	3 (75.0)	0	0	9 (69.2)
Fibrinogen from time0 until 24 hours after time0, N (%)				
Yes	1 (25.0)	1 (100.0)	0	1 (7.7)
No	3 (75.0)	0	0	12 (92.3)

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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	Trauma	Other
Number of patients	0	0
Tranexamic acid from delivery to time0, N (%)		
Yes	0	0
No	0	0
Tranexamic acid from time0 until 24 hours after time0, N (%)		
Yes	0	0
No	0	0
Tranexamic acid overall*, N (%)		
Yes	0	0
No	0	0
Fibrinogen from delivery to time0, N (%)		
Yes	0	0
No	0	0
Fibrinogen from time0 until 24 hours after time0, N (%)		
Yes	0	0
No	0	0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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	AIP	Placental abruption	Placental retention	Uterine Atony
Fibrinogen overall*, N (%)				
Yes	2 (50.0)	1 (100.0)	0	5 (38.5)
No	2 (50.0)	0	0	8 (61.5)
Oxytocin from delivery to time0 (count)				
N	4	1	0	11
Mean (SD)	1.8 (1.0)	3.0 (NE)		2.4 (1.5)
Median (IQR)	1.5 (1.0 - 2.5)	3.0 (3.0 - 3.0)		2.0 (1.0 - 3.0)
Min ; Max	1 ; 3	3 ; 3		1 ; 6
Oxytocin from time0 until 24 hours after time0 (count)				
N	2	1	0	6
Mean (SD)	1.0 (0.0)	1.0 (NE)		1.2 (0.4)
Median (IQR)	1.0 (1.0 - 1.0)	1.0 (1.0 - 1.0)		1.0 (1.0 - 1.0)
Min ; Max	1 ; 1	1 ; 1		1 ; 2
Oxytocin overall* (count)				
N	4	1	0	11
Mean (SD)	2.0 (1.2)	3.0 (NE)		2.7 (1.5)
Median (IQR)	2.0 (1.0 - 3.0)	3.0 (3.0 - 3.0)		2.0 (2.0 - 4.0)
Min ; Max	1 ; 3	3 ; 3		1 ; 6
Other uterotonics from delivery to time0 (count)				
N	4	0	0	11
Mean (SD)	1.8 (0.5)			1.6 (0.9)
Median (IQR)	2.0 (1.5 - 2.0)			1.0 (1.0 - 2.0)
Min ; Max	1 ; 2			1 ; 4

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	Trauma	Other
Fibrinogen overall*, N (%)		
Yes	0	0
No	0	0
Oxytocin from delivery to time0 (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Oxytocin from time0 until 24 hours after time0 (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Oxytocin overall* (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Other uterotonics from delivery to time0 (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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	AIP	Placental abruption	Placental retention	Uterine Atony
Other uterotonics from time0 until 24 hours after time0 (count)				
N	2	1	0	6
Mean (SD)	1.0 (0.0)	2.0 (NE)		1.3 (0.5)
Median (IQR)	1.0 (1.0 - 1.0)	2.0 (2.0 - 2.0)		1.0 (1.0 - 2.0)
Min ; Max	1 ; 1	2 ; 2		1 ; 2
Other uterotonics overall* (count)				
N	4	1	0	12
Mean (SD)	2.3 (1.0)	2.0 (NE)		2.0 (0.9)
Median (IQR)	2.5 (1.5 - 3.0)	2.0 (2.0 - 2.0)		2.0 (1.5 - 2.0)
Min ; Max	1 ; 3	2 ; 2		1 ; 4
Colloids from delivery to time0 (mL)				
N	4	1	0	9
Mean (SD)	1250.0 (957.4)	2000.0 (NE)		1055.6 (527.0)
Median (IQR)	1000.0 (500.0 - 2000.0)	2000.0 (2000.0 - 2000.0)		1000.0 (500.0 - 1500.0)
Min ; Max	500 ; 2500	2000 ; 2000		500 ; 2000
Colloids from time0 until 24 hours after time0 (mL)				
N	1	0	0	4
Mean (SD)	500.0 (NE)			625.0 (250.0)
Median (IQR)	500.0 (500.0 - 500.0)			500.0 (500.0 - 750.0)
Min ; Max	500 ; 500			500 ; 1000

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	Trauma	Other
Other uterotonics from time0 until 24 hours after time0 (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Other uterotonics overall* (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Colloids from delivery to time0 (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Colloids from time0 until 24 hours after time0 (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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	AIP	Placental abruption	Placental retention	Uterine Atony
Colloids overall* (mL)				
N	4	1	0	10
Mean (SD)	1375.0 (853.9)	2000.0 (NE)		1200.0 (674.9)
Median (IQR)	1250.0 (750.0 - 2000.0)	2000.0 (2000.0 - 2000.0)		1000.0 (500.0 - 1500.0)
Min ; Max	500 ; 2500	2000 ; 2000		500 ; 2500
Crystalloids from delivery to time0 (mL)				
N	4	1	0	10
Mean (SD)	1550.0 (881.3)	3200.0 (NE)		1660.0 (1238.5)
Median (IQR)	1600.0 (850.0 - 2250.0)	3200.0 (3200.0 - 3200.0)		1250.0 (1000.0 - 2000.0)
Min ; Max	500 ; 2500	3200 ; 3200		500 ; 4500
Crystalloids from time0 until 24 hours after time0 (mL)				
N	4	1	0	8
Mean (SD)	1925.0 (809.8)	1200.0 (NE)		1537.5 (697.3)
Median (IQR)	2000.0 (1250.0 - 2600.0)	1200.0 (1200.0 - 1200.0)		1275.0 (1000.0 - 1875.0)
Min ; Max	1000 ; 2700	1200 ; 1200		1000 ; 3000
Crystalloids overall* (mL)				
N	4	1	0	11
Mean (SD)	2675.0 (1090.5)	3300.0 (NE)		2150.0 (1296.7)
Median (IQR)	2750.0 (1750.0 - 3600.0)	3300.0 (3300.0 - 3300.0)		2000.0 (1000.0 - 3000.0)
Min ; Max	1500 ; 3700	3300 ; 3300		500 ; 4500

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	Trauma	Other
Colloids overall* (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Crystalloids from delivery to time0 (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Crystalloids from time0 until 24 hours after time0 (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Crystalloids overall* (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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	AIP	Placental abruption	Placental retention	Uterine Atony
Red blood cells from delivery to time0 (count)				
N	4	1	0	11
Mean (SD)	4.5 (3.3)	4.0 (NE)		4.3 (3.0)
Median (IQR)	3.5 (2.0 - 7.0)	4.0 (4.0 - 4.0)		4.0 (1.0 - 6.0)
Min ; Max	2 ; 9	4 ; 4		1 ; 10
Red blood cells from time0 until 24 hours after time0 (count)				
N	3	1	0	11
Mean (SD)	10.7 (8.6)	5.0 (NE)		6.4 (4.1)
Median (IQR)	9.0 (3.0 - 20.0)	5.0 (5.0 - 5.0)		6.0 (3.0 - 10.0)
Min ; Max	3 ; 20	5 ; 5		1 ; 14
Red blood cells overall* (count)				
N	4	1	0	13
Mean (SD)	12.5 (11.6)	9.0 (NE)		8.9 (5.3)
Median (IQR)	9.5 (5.0 - 20.0)	9.0 (9.0 - 9.0)		8.0 (6.0 - 12.0)
Min ; Max	2 ; 29	9 ; 9		1 ; 19

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	Trauma	Other
Red blood cells from delivery to time0 (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Red blood cells from time0 until 24 hours after time0 (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Red blood cells overall* (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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	AIP	Placental abruption	Placental retention	Uterine Atony
Red blood cells from delivery to time0 (mL)				
N	4	1	0	11
Mean (SD)	1237.5 (912.1)	1100.0 (NE)		1175.0 (834.9)
Median (IQR)	962.5 (550.0 - 1925.0)	1100.0 (1100.0 - 1100.0)		1100.0 (275.0 - 1650.0)
Min ; Max	550 ; 2475	1100 ; 1100		275 ; 2750
Red blood cells from time0 until 24 hours after time0 (mL)				
N	3	1	0	11
Mean (SD)	2933.3 (2371.0)	1375.0 (NE)		1750.0 (1122.3)
Median (IQR)	2475.0 (825.0 - 5500.0)	1375.0 (1375.0 - 1375.0)		1650.0 (825.0 - 2750.0)
Min ; Max	825 ; 5500	1375 ; 1375		275 ; 3850
Red blood cells overall* (mL)				
N	4	1	0	13
Mean (SD)	3437.5 (3195.2)	2475.0 (NE)		2453.8 (1465.8)
Median (IQR)	2612.5 (1375.0 - 5500.0)	2475.0 (2475.0 - 2475.0)		2200.0 (1650.0 - 3300.0)
Min ; Max	550 ; 7975	2475 ; 2475		275 ; 5225

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	Trauma	Other
Red blood cells from delivery to time0 (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Red blood cells from time0 until 24 hours after time0 (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Red blood cells overall* (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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	AIP	Placental abruption	Placental retention	Uterine Atony
FFP transfusion from delivery to time0 (count)				
N	4	1	0	9
Mean (SD)	4.5 (3.1)	6.0 (NE)		4.1 (3.3)
Median (IQR)	3.5 (2.5 - 6.5)	6.0 (6.0 - 6.0)		3.0 (2.0 - 4.0)
Min ; Max	2 ; 9	6 ; 6		1 ; 10
FFP transfusion from time0 until 24 hours after time0 (count)				
N	3	1	0	13
Mean (SD)	10.0 (11.5)	5.0 (NE)		5.0 (4.4)
Median (IQR)	6.0 (1.0 - 23.0)	5.0 (5.0 - 5.0)		4.0 (2.0 - 7.0)
Min ; Max	1 ; 23	5 ; 5		1 ; 17
FFP transfusion overall* (count)				
N	4	1	0	13
Mean (SD)	12.0 (13.5)	9.0 (NE)		7.8 (4.7)
Median (IQR)	6.0 (4.0 - 20.0)	9.0 (9.0 - 9.0)		8.0 (5.0 - 10.0)
Min ; Max	4 ; 32	9 ; 9		1 ; 19

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	Trauma	Other
FFP transfusion from delivery to time0 (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
FFP transfusion from time0 until 24 hours after time0 (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
FFP transfusion overall* (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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	AIP	Placental abruption	Placental retention	Uterine Atony
FFP transfusion from delivery to time0 (mL)				
N	4	1	0	9
Mean (SD)	1260.0 (870.6)	1680.0 (NE)		1151.1 (912.1)
Median (IQR)	980.0 (700.0 - 1820.0)	1680.0 (1680.0 - 1680.0)		840.0 (560.0 - 1120.0)
Min ; Max	560 ; 2520	1680 ; 1680		280 ; 2800
FFP transfusion from time0 until 24 hours after time0 (mL)				
N	3	1	0	13
Mean (SD)	2800.0 (3229.1)	1400.0 (NE)		1400.0 (1231.2)
Median (IQR)	1680.0 (280.0 - 6440.0)	1400.0 (1400.0 - 1400.0)		1120.0 (560.0 - 1960.0)
Min ; Max	280 ; 6440	1400 ; 1400		280 ; 4760
FFP transfusion overall* (mL)				
N	4	1	0	13
Mean (SD)	3360.0 (3770.5)	2520.0 (NE)		2175.4 (1314.1)
Median (IQR)	1680.0 (1120.0 - 5600.0)	2520.0 (2520.0 - 2520.0)		2240.0 (1400.0 - 2800.0)
Min ; Max	1120 ; 8960	2520 ; 2520		280 ; 5320

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated. The unit 'counts' indicates the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

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	Trauma	Other
FFP transfusion from delivery to time0 (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
FFP transfusion from time0 until 24 hours after time0 (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
FFP transfusion overall* (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Concomitant medications - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony
Platelets from delivery to time0 (count)				
N	2	0	0	2
Mean (SD)	1.0 (0.0)			1.0 (0.0)
Median (IQR)	1.0 (1.0 - 1.0)			1.0 (1.0 - 1.0)
Min ; Max	1 ; 1			1 ; 1
Platelets from time0 until 24 hours after time0 (count)				
N	2	1	0	5
Mean (SD)	1.5 (0.7)	1.0 (NE)		1.6 (0.9)
Median (IQR)	1.5 (1.0 - 2.0)	1.0 (1.0 - 1.0)		1.0 (1.0 - 2.0)
Min ; Max	1 ; 2	1 ; 1		1 ; 3
Platelets overall* (count)				
N	3	1	0	6
Mean (SD)	1.7 (1.2)	1.0 (NE)		1.5 (0.8)
Median (IQR)	1.0 (1.0 - 3.0)	1.0 (1.0 - 1.0)		1.0 (1.0 - 2.0)
Min ; Max	1 ; 3	1 ; 1		1 ; 3

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated. The unit 'counts' indicates the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

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	Trauma	Other
Platelets from delivery to time0 (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Platelets from time0 until 24 hours after time0 (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Platelets overall* (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated. The unit 'counts' indicates the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony
Platelets from delivery to time0 (mL)				
N	2	0	0	2
Mean (SD)	125.0 (0.0)			125.0 (0.0)
Median (IQR)	125.0 (125.0 - 125.0)			125.0 (125.0 - 125.0)
Min ; Max	125 ; 125			125 ; 125
Platelets from time0 until 24 hours after time0 (mL)				
N	2	1	0	5
Mean (SD)	187.5 (88.4)	125.0 (NE)		200.0 (111.8)
Median (IQR)	187.5 (125.0 - 250.0)	125.0 (125.0 - 125.0)		125.0 (125.0 - 250.0)
Min ; Max	125 ; 250	125 ; 125		125 ; 375
Platelets overall* (mL)				
N	3	1	0	6
Mean (SD)	208.3 (144.3)	125.0 (NE)		187.5 (104.6)
Median (IQR)	125.0 (125.0 - 375.0)	125.0 (125.0 - 125.0)		125.0 (125.0 - 250.0)
Min ; Max	125 ; 375	125 ; 125		125 ; 375

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated. The unit 'counts' indicates the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

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	Trauma	Other
Platelets from delivery to time0 (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Platelets from time0 until 24 hours after time0 (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Platelets overall* (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated. The unit 'counts' indicates the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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14.1.17 Concomitant medications - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony
Number of patients	14	3	0	23
Number of weighted patients, N	5.0	2.3	0	8.4
Tranexamic acid from delivery to time0, N (%)				
Yes	3.3 (66.7)	1.3 (55.6)	0	3.1 (36.6)
No	1.7 (33.3)	1.0 (44.4)	0	5.3 (63.4)
Tranexamic acid from time0 until 24 hours after time0, N (%)				
Yes	0.9 (18.3)	2.0 (88.9)	0	3.0 (35.6)
No	4.1 (81.7)	0.3 (11.1)	0	5.4 (64.4)
Tranexamic acid overall*, N (%)				
Yes	4.5 (90.0)	2.3 (100.0)	0	4.8 (57.4)
No	0.5 (10.0)	0	0	3.6 (42.6)
Fibrinogen from delivery to time0, N (%)				
Yes	0.8 (16.7)	0	0	1.8 (20.8)
No	4.2 (83.3)	2.3 (100.0)	0	6.7 (79.2)
Fibrinogen from time0 until 24 hours after time0, N (%)				
Yes	0.8 (15.0)	0.3 (11.1)	0	2.6 (30.7)
No	4.3 (85.0)	2.0 (88.9)	0	5.8 (69.3)

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	Trauma	Other
Number of patients	2	1
Number of weighted patients, N	1.3	1.0
Tranexamic acid from delivery to time0, N (%)		
Yes	0.3 (25.0)	0
No	1.0 (75.0)	1.0 (100.0)
Tranexamic acid from time0 until 24 hours after time0, N (%)		
Yes	1.0 (75.0)	1.0 (100.0)
No	0.3 (25.0)	0
Tranexamic acid overall*, N (%)		
Yes	1.3 (100.0)	1.0 (100.0)
No	0	0
Fibrinogen from delivery to time0, N (%)		
Yes	0	0
No	1.3 (100.0)	1.0 (100.0)
Fibrinogen from time0 until 24 hours after time0, N (%)		
Yes	0	0
No	1.3 (100.0)	1.0 (100.0)

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony
Fibrinogen overall*, N (%)				
Yes	1.6 (31.7)	0	0	4.3 (51.5)
No	3.4 (68.3)	2.3 (100.0)	0	4.1 (48.5)
Oxytocin from delivery to time0 (count)				
N	3.3	2.3	0	7.7
Mean (SD)	2.2 (0.6)	2.3 (0.7)		2.3 (1.1)
Median (IQR)	3.0 (1.0 - 3.0)	2.0 (2.0 - 3.0)		2.0 (1.0 - 3.0)
Min ; Max	1 ; 3	1 ; 3		1 ; 6
Oxytocin from time0 until 24 hours after time0 (count)				
N	2.8	1.0	0	3.5
Mean (SD)	1.6 (0.8)	2.0 (NE)		1.4 (0.3)
Median (IQR)	1.0 (1.0 - 2.0)	2.0 (2.0 - 2.0)		1.0 (1.0 - 2.0)
Min ; Max	1 ; 4	2 ; 2		1 ; 2
Oxytocin overall* (count)				
N	4.0	2.3	0	7.9
Mean (SD)	3.0 (1.3)	3.2 (1.0)		2.6 (1.1)
Median (IQR)	3.0 (1.0 - 4.5)	3.0 (3.0 - 4.0)		2.0 (1.0 - 4.0)
Min ; Max	1 ; 6	1 ; 4		1 ; 6
Other uterotonics from delivery to time0 (count)				
N	4.0	1.3	0	5.7
Mean (SD)	1.7 (0.4)	1.0 (0.0)		2.1 (0.8)
Median (IQR)	2.0 (1.0 - 2.0)	1.0 (1.0 - 1.0)		1.5 (1.0 - 4.0)
Min ; Max	1 ; 3	1 ; 1		1 ; 4

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	Trauma	Other
Fibrinogen overall*, N (%)		
Yes	0	0
No	1.3 (100.0)	1.0 (100.0)
Oxytocin from delivery to time0 (count)		
N	1.0	1.0
Mean (SD)	1.0 (NE)	2.0 (NE)
Median (IQR)	1.0 (1.0 - 1.0)	2.0 (2.0 - 2.0)
Min ; Max	1 ; 1	2 ; 2
Oxytocin from time0 until 24 hours after time0 (count)		
N	0	1.0
Mean (SD)		2.0 (NE)
Median (IQR)		2.0 (2.0 - 2.0)
Min ; Max		2 ; 2
Oxytocin overall* (count)		
N	1.0	1.0
Mean (SD)	1.0 (NE)	4.0 (NE)
Median (IQR)	1.0 (1.0 - 1.0)	4.0 (4.0 - 4.0)
Min ; Max	1 ; 1	4 ; 4
Other uterotonics from delivery to time0 (count)		
N	1.0	0
Mean (SD)	1.0 (NE)	
Median (IQR)	1.0 (1.0 - 1.0)	
Min ; Max	1 ; 1	

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

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	AIP	Placental abruption	Placental retention	Uterine Atony
Other uterotonics from time0 until 24 hours after time0 (count)				
N	1.0	1.3	0	4.5
Mean (SD)	1.8 (0.3)	1.2 (0.4)		1.4 (0.4)
Median (IQR)	2.0 (1.5 - 2.0)	1.0 (1.0 - 1.0)		1.0 (1.0 - 2.0)
Min ; Max	1 ; 2	1 ; 2		1 ; 3
Other uterotonics overall* (count)				
N	4.3	1.3	0	6.9
Mean (SD)	2.0 (0.4)	2.0 (0.0)		2.5 (0.6)
Median (IQR)	2.0 (2.0 - 2.0)	2.0 (2.0 - 2.0)		2.0 (2.0 - 4.0)
Min ; Max	1 ; 3	2 ; 2		1 ; 4
Colloids from delivery to time0 (mL)				
N	4.3	2.0	0	7.4
Mean (SD)	1274.5 (424.8)	1250.0 (1060.7)		915.7 (337.6)
Median (IQR)	1500.0 (500.0 - 2000.0)	1250.0 (500.0 - 2000.0)		500.0 (500.0 - 1500.0)
Min ; Max	500 ; 2000	500 ; 2000		500 ; 2000
Colloids from time0 until 24 hours after time0 (mL)				
N	2.8	2.0	0	4.1
Mean (SD)	544.1 (97.5)	1000.0 (707.1)		1244.9 (373.4)
Median (IQR)	500.0 (500.0 - 500.0)	1000.0 (500.0 - 1500.0)		1500.0 (1000.0 - 1500.0)
Min ; Max	500 ; 1000	500 ; 1500		500 ; 2500

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	Trauma	Other
Other uterotonics from time0 until 24 hours after time0 (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Other uterotonics overall* (count)		
N	1.0	0
Mean (SD)	1.0 (NE)	
Median (IQR)	1.0 (1.0 - 1.0)	
Min ; Max	1 ; 1	
Colloids from delivery to time0 (mL)		
N	1.3	1.0
Mean (SD)	2250.0 (500.0)	1000.0 (NE)
Median (IQR)	2500.0 (2000.0 - 2500.0)	1000.0 (1000.0 - 1000.0)
Min ; Max	1500 ; 2500	1000 ; 1000
Colloids from time0 until 24 hours after time0 (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony
Colloids overall* (mL)				
N	4.3	2.0	0	8.2
Mean (SD)	1902.0 (727.5)	2250.0 (353.6)		1454.1 (630.1)
Median (IQR)	1500.0 (500.0 - 2500.0)	2250.0 (2000.0 - 2500.0)		1000.0 (500.0 - 2000.0)
Min ; Max	500 ; 3500	2000 ; 2500		500 ; 4000
Crystalloids from delivery to time0 (mL)				
N	4.8	2.3	0	7.9
Mean (SD)	1394.7 (453.1)	3044.4 (1108.1)		2093.2 (983.4)
Median (IQR)	1000.0 (1000.0 - 2200.0)	2500.0 (2500.0 - 4100.0)		2300.0 (500.0 - 2500.0)
Min ; Max	500 ; 2700	1000 ; 4100		500 ; 7000
Crystalloids from time0 until 24 hours after time0 (mL)				
N	5.0	2.3	0	6.8
Mean (SD)	1877.5 (784.9)	2055.6 (1871.6)		2219.5 (862.9)
Median (IQR)	1500.0 (1000.0 - 2100.0)	1300.0 (300.0 - 4000.0)		2000.0 (1300.0 - 2850.0)
Min ; Max	100 ; 4800	300 ; 4000		1000 ; 8000
Crystalloids overall* (mL)				
N	5.0	2.3	0	8.2
Mean (SD)	2855.8 (738.3)	5066.7 (1557.2)		3390.3 (1094.7)
Median (IQR)	3000.0 (2000.0 - 4000.0)	4400.0 (4400.0 - 6500.0)		2900.0 (2500.0 - 4500.0)
Min ; Max	1000 ; 4500	2000 ; 6500		500 ; 7000

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	Trauma	Other
Colloids overall* (mL)		
N	1.3	1.0
Mean (SD)	2250.0 (500.0)	1000.0 (NE)
Median (IQR)	2500.0 (2000.0 - 2500.0)	1000.0 (1000.0 - 1000.0)
Min ; Max	1500 ; 2500	1000 ; 1000
Crystalloids from delivery to time0 (mL)		
N	1.0	1.0
Mean (SD)	3100.0 (NE)	3000.0 (NE)
Median (IQR)	3100.0 (3100.0 - 3100.0)	3000.0 (3000.0 - 3000.0)
Min ; Max	3100 ; 3100	3000 ; 3000
Crystalloids from time0 until 24 hours after time0 (mL)		
N	0	1.0
Mean (SD)		1000.0 (NE)
Median (IQR)		1000.0 (1000.0 - 1000.0)
Min ; Max		1000 ; 1000
Crystalloids overall* (mL)		
N	1.0	1.0
Mean (SD)	3100.0 (NE)	4000.0 (NE)
Median (IQR)	3100.0 (3100.0 - 3100.0)	4000.0 (4000.0 - 4000.0)
Min ; Max	3100 ; 3100	4000 ; 4000

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony
1.0				
	Red blood cells from delivery to time0 (count)			
	N	4.3	2.0	5.7
	Mean (SD)	4.3 (1.6)	8.0 (2.8)	3.8 (0.9)
	Median (IQR)	3.0 (2.0 - 6.0)	8.0 (6.0 - 10.0)	4.0 (3.0 - 5.0)
	Min ; Max	1 ; 8	6 ; 10	2 ; 6
	Red blood cells from time0 until 24 hours after time0 (count)			
	N	3.7	2.3	8.2
	Mean (SD)	7.1 (4.2)	9.4 (4.3)	8.3 (3.2)
	Median (IQR)	3.0 (2.0 - 8.0)	6.0 (6.0 - 14.0)	8.0 (4.0 - 11.0)
	Min ; Max	2 ; 23	5 ; 14	1 ; 18
	Red blood cells overall* (count)			
	N	4.8	2.3	8.2
	Mean (SD)	10.0 (4.9)	16.3 (7.8)	10.5 (3.8)
	Median (IQR)	9.0 (4.0 - 12.0)	12.0 (12.0 - 24.0)	9.5 (6.0 - 14.0)
	Min ; Max	1 ; 29	3 ; 24	2 ; 22

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	Trauma	Other
1.0		
	Red blood cells from delivery to time0 (count)	
	N	1.3
	Mean (SD)	3.5 (1.0)
	Median (IQR)	4.0 (3.0 - 4.0)
	Min ; Max	2 ; 4
	Red blood cells from time0 until 24 hours after time0 (count)	
	N	1.0
	Mean (SD)	7.8 (4.5)
	Median (IQR)	10.0 (5.5 - 10.0)
	Min ; Max	1 ; 10
	Red blood cells overall* (count)	
	N	1.0
	Mean (SD)	8.3 (3.5)
	Median (IQR)	10.0 (6.5 - 10.0)
	Min ; Max	3 ; 10

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony
Red blood cells from delivery to time0 (mL)				
N	4.3	2.0	0	5.7
Mean (SD)	1191.7 (443.0)	2200.0 (777.8)		1051.5 (241.6)
Median (IQR)	825.0 (550.0 - 1650.0)	2200.0 (1650.0 - 2750.0)		1100.0 (825.0 - 1375.0)
Min ; Max	275 ; 2200	1650 ; 2750		550 ; 1650
Red blood cells from time0 until 24 hours after time0 (mL)				
N	3.7	2.3	0	8.2
Mean (SD)	1956.3 (1147.0)	2597.2 (1191.7)		2284.2 (883.8)
Median (IQR)	825.0 (550.0 - 2200.0)	1650.0 (1650.0 - 3850.0)		2200.0 (1100.0 - 3025.0)
Min ; Max	550 ; 6325	1375 ; 3850		275 ; 4950
Red blood cells overall* (mL)				
N	4.8	2.3	0	8.2
Mean (SD)	2754.8 (1339.2)	4491.7 (2147.8)		2879.1 (1042.1)
Median (IQR)	2475.0 (1100.0 - 3300.0)	3300.0 (3300.0 - 6600.0)		2612.5 (1650.0 - 3850.0)
Min ; Max	275 ; 7975	825 ; 6600		550 ; 6050

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	Trauma	Other
Red blood cells from delivery to time0 (mL)		
N	1.3	1.0
Mean (SD)	962.5 (275.0)	550.0 (NE)
Median (IQR)	1100.0 (825.0 - 1100.0)	550.0 (550.0 - 550.0)
Min ; Max	550 ; 1100	550 ; 550
Red blood cells from time0 until 24 hours after time0 (mL)		
N	1.3	1.0
Mean (SD)	2131.3 (1237.5)	1925.0 (NE)
Median (IQR)	2750.0 (1512.5 - 2750.0)	1925.0 (1925.0 - 1925.0)
Min ; Max	275 ; 2750	1925 ; 1925
Red blood cells overall* (mL)		
N	1.3	1.0
Mean (SD)	2268.8 (962.5)	2475.0 (NE)
Median (IQR)	2750.0 (1787.5 - 2750.0)	2475.0 (2475.0 - 2475.0)
Min ; Max	825 ; 2750	2475 ; 2475

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Non-interventional report
Report body

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony
FFP transfusion from delivery to time0 (count)				
N	3.7	2.3	0	5.4
Mean (SD)	4.1 (1.9)	6.3 (3.6)		3.2 (0.7)
Median (IQR)	3.0 (1.0 - 8.0)	4.0 (4.0 - 10.0)		3.0 (3.0 - 4.0)
Min ; Max	1 ; 8	1 ; 10		1 ; 5
FFP transfusion from time0 until 24 hours after time0 (count)				
N	3.1	2.3	0	6.9
Mean (SD)	6.9 (5.1)	8.1 (4.8)		6.8 (1.7)
Median (IQR)	2.0 (2.0 - 5.0)	5.0 (5.0 - 13.0)		7.0 (5.0 - 8.0)
Min ; Max	1 ; 26	1 ; 13		2 ; 14
FFP transfusion overall* (count)				
N	4.2	2.3	0	7.9
Mean (SD)	9.8 (5.8)	14.4 (8.4)		8.0 (2.0)
Median (IQR)	6.0 (4.0 - 12.0)	9.0 (9.0 - 23.0)		8.0 (5.0 - 11.0)
Min ; Max	2 ; 32	2 ; 23		2 ; 14

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	Trauma	Other
1.0		
	FFP transfusion from delivery to time0 (count)	
	N	1.0
	Mean (SD)	3.5 (1.0) 4.0 (NE)
	Median (IQR)	4.0 (3.0 - 4.0) 4.0 (4.0 - 4.0)
	Min ; Max	2 ; 4 4 ; 4
	FFP transfusion from time0 until 24 hours after time0 (count)	
	N	1.0
	Mean (SD)	7.0 (NE) 9.0 (NE)
	Median (IQR)	7.0 (7.0 - 7.0) 9.0 (9.0 - 9.0)
	Min ; Max	7 ; 7 9 ; 9
	FFP transfusion overall* (count)	
	N	1.0
	Mean (SD)	6.5 (3.0) 13.0 (NE)
	Median (IQR)	8.0 (5.0 - 8.0) 13.0 (13.0 - 13.0)
	Min ; Max	2 ; 8 13 ; 13

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony
FFP transfusion from delivery to time0 (mL)				
N	3.7	2.3	0	5.4
Mean (SD)	1151.8 (541.0)	1773.3 (1009.6)		891.7 (194.3)
Median (IQR)	840.0 (280.0 - 2240.0)	1120.0 (1120.0 - 2800.0)		840.0 (840.0 - 1120.0)
Min ; Max	280 ; 2240	280 ; 2800		280 ; 1400
FFP transfusion from time0 until 24 hours after time0 (mL)				
N	3.1	2.3	0	6.9
Mean (SD)	1944.9 (1439.3)	2271.1 (1346.1)		1899.3 (465.9)
Median (IQR)	560.0 (560.0 - 1400.0)	1400.0 (1400.0 - 3640.0)		1960.0 (1400.0 - 2240.0)
Min ; Max	280 ; 7280	280 ; 3640		560 ; 3920
FFP transfusion overall* (mL)				
N	4.2	2.3	0	7.9
Mean (SD)	2738.4 (1631.2)	4044.4 (2355.6)		2242.9 (549.7)
Median (IQR)	1680.0 (1120.0 - 3360.0)	2520.0 (2520.0 - 6440.0)		2240.0 (1400.0 - 3080.0)
Min ; Max	560 ; 8960	560 ; 6440		560 ; 3920

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	Trauma	Other
FFP transfusion from delivery to time0 (mL)		
N	1.3	1.0
Mean (SD)	980.0 (280.0)	1120.0 (NE)
Median (IQR)	1120.0 (840.0 - 1120.0)	1120.0 (1120.0 - 1120.0)
Min ; Max	560 ; 1120	1120 ; 1120
FFP transfusion from time0 until 24 hours after time0 (mL)		
N	1.0	1.0
Mean (SD)	1960.0 (NE)	2520.0 (NE)
Median (IQR)	1960.0 (1960.0 - 1960.0)	2520.0 (2520.0 - 2520.0)
Min ; Max	1960 ; 1960	2520 ; 2520
FFP transfusion overall* (mL)		
N	1.3	1.0
Mean (SD)	1820.0 (840.0)	3640.0 (NE)
Median (IQR)	2240.0 (1400.0 - 2240.0)	3640.0 (3640.0 - 3640.0)
Min ; Max	560 ; 2240	3640 ; 3640

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony
1.0	Platelets from delivery to time0 (count)			
	N	1.0	0	1.0
	Mean (SD)	1.0 (NE)		1.0 (NE)
	Median (IQR)	1.0 (1.0 - 1.0)		1.0 (1.0 - 1.0)
	Min ; Max	1 ; 1		1 ; 1
	Platelets from time0 until 24 hours after time0 (count)			
	N	2.0	0	4.2
	Mean (SD)	2.5 (0.7)		1.2 (0.3)
	Median (IQR)	2.5 (2.0 - 3.0)		1.0 (1.0 - 1.0)
	Min ; Max	2 ; 3		1 ; 2
	Platelets overall* (count)			
	N	2.0	0	3.8
	Mean (SD)	3.0 (0.0)		1.5 (0.3)
	Median (IQR)	3.0 (3.0 - 3.0)		2.0 (1.0 - 2.0)
	Min ; Max	3 ; 3		1 ; 2

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

1.0

	Trauma	Other
Platelets from delivery to time0 (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Platelets from time0 until 24 hours after time0 (count)		
N	1.0	1.0
Mean (SD)	2.0 (NE)	3.0 (NE)
Median (IQR)	2.0 (2.0 - 2.0)	3.0 (3.0 - 3.0)
Min ; Max	2 ; 2	3 ; 3
Platelets overall* (count)		
N	1.0	1.0
Mean (SD)	1.0 (NE)	3.0 (NE)
Median (IQR)	1.0 (1.0 - 1.0)	3.0 (3.0 - 3.0)
Min ; Max	1 ; 1	3 ; 3

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony
Platelets from delivery to time0 (mL)				
N	1.5	1.0	0	1.0
Mean (SD)	125.0 (0.0)	125.0 (NE)		125.0 (NE)
Median (IQR)	125.0 (125.0 - 125.0)	125.0 (125.0 - 125.0)		125.0 (125.0 - 125.0)
Min ; Max	125 ; 125	125 ; 125		125 ; 125
Platelets from time0 until 24 hours after time0 (mL)				
N	1.5	2.0	0	4.2
Mean (SD)	333.3 (65.9)	312.5 (88.4)		155.0 (32.9)
Median (IQR)	375.0 (375.0 - 375.0)	312.5 (250.0 - 375.0)		125.0 (125.0 - 125.0)
Min ; Max	125 ; 375	250 ; 375		125 ; 250
Platelets overall* (mL)				
N	2.5	2.0	0	3.8
Mean (SD)	275.0 (123.4)	375.0 (0.0)		190.2 (38.7)
Median (IQR)	250.0 (125.0 - 375.0)	375.0 (375.0 - 375.0)		250.0 (125.0 - 250.0)
Min ; Max	125 ; 500	375 ; 375		125 ; 250

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by cause of PPH for matched controls - PS analysis set

	Trauma	Other
Platelets from delivery to time0 (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Platelets from time0 until 24 hours after time0 (mL)		
N	1.0	1.0
Mean (SD)	250.0 (NE)	375.0 (NE)
Median (IQR)	250.0 (250.0 - 250.0)	375.0 (375.0 - 375.0)
Min ; Max	250 ; 250	375 ; 375
Platelets overall* (mL)		
N	1.0	1.0
Mean (SD)	125.0 (NE)	375.0 (NE)
Median (IQR)	125.0 (125.0 - 125.0)	375.0 (375.0 - 375.0)
Min ; Max	125 ; 125	375 ; 375

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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14.1.18 Concomitant medications - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
1.0 Number of patients	2	0	15
Tranexamic acid from delivery to time0, N (%)			
Yes	1 (50.0)	0	9 (60.0)
No	1 (50.0)	0	6 (40.0)
Tranexamic acid from time0 until 24 hours after time0, N (%)			
Yes	1 (50.0)	0	2 (13.3)
No	1 (50.0)	0	13 (86.7)
Tranexamic acid overall*, N (%)			
Yes	2 (100.0)	0	11 (73.3)
No	0	0	4 (26.7)
Fibrinogen from delivery to time0, N (%)			
Yes	0	0	6 (40.0)
No	2 (100.0)	0	9 (60.0)
Fibrinogen from time0 until 24 hours after time0, N (%)			
Yes	1 (50.0)	0	2 (13.3)
No	1 (50.0)	0	13 (86.7)

PS: Propensity score, N: Number of patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated. Oxytocin and other uterotonics are summarised based on the number of doses Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

Concomitant medications - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	After first invasive procedure	Missing
1.0 Number of patients	1	0
Tranexamic acid from delivery to time0, N (%)		
Yes	0	0
No	1 (100.0)	0
Tranexamic acid from time0 until 24 hours after time0, N (%)		
Yes	0	0
No	1 (100.0)	0
Tranexamic acid overall*, N (%)		
Yes	0	0
No	1 (100.0)	0
Fibrinogen from delivery to time0, N (%)		
Yes	0	0
No	1 (100.0)	0
Fibrinogen from time0 until 24 hours after time0, N (%)		
Yes	0	0
No	1 (100.0)	0

PS: Propensity score, N: Number of patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
Fibrinogen overall*, N (%)			
Yes	1 (50.0)	0	7 (46.7)
No	1 (50.0)	0	8 (53.3)
Oxytocin from delivery to time0 (count)			
N	1	0	14
Mean (SD)	2.0 (NE)		2.2 (1.4)
Median (IQR)	2.0 (2.0 - 2.0)		2.0 (1.0 - 3.0)
Min ; Max	2 ; 2		1 ; 6
Oxytocin from time0 until 24 hours after time0 (count)			
N	1	0	7
Mean (SD)	1.0 (NE)		1.1 (0.4)
Median (IQR)	1.0 (1.0 - 1.0)		1.0 (1.0 - 1.0)
Min ; Max	1 ; 1		1 ; 2
Oxytocin overall* (count)			
N	1	0	14
Mean (SD)	3.0 (NE)		2.4 (1.4)
Median (IQR)	3.0 (3.0 - 3.0)		2.0 (1.0 - 3.0)
Min ; Max	3 ; 3		1 ; 6
Other uterotonics from delivery to time0 (count)			
N	2	0	13
Mean (SD)	1.5 (0.7)		1.7 (0.9)
Median (IQR)	1.5 (1.0 - 2.0)		2.0 (1.0 - 2.0)
Min ; Max	1 ; 2		1 ; 4

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Concomitant medications - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	After first invasive procedure	Missing
Fibrinogen overall*, N (%)		
Yes	0	0
No	1 (100.0)	0
Oxytocin from delivery to time0 (count)		
N	1	0
Mean (SD)	3.0 (NE)	
Median (IQR)	3.0 (3.0 - 3.0)	
Min ; Max	3 ; 3	
Oxytocin from time0 until 24 hours after time0 (count)		
N	1	0
Mean (SD)	1.0 (NE)	
Median (IQR)	1.0 (1.0 - 1.0)	
Min ; Max	1 ; 1	
Oxytocin overall* (count)		
N	1	0
Mean (SD)	4.0 (NE)	
Median (IQR)	4.0 (4.0 - 4.0)	
Min ; Max	4 ; 4	
Other uterotonics from delivery to time0 (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

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	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
Other uterotonics from time0 until 24 hours after time0 (count)			
N	1	0	8
Mean (SD)	1.0 (NE)		1.4 (0.5)
Median (IQR)	1.0 (1.0 - 1.0)		1.0 (1.0 - 2.0)
Min ; Max	1 ; 1		1 ; 2
Other uterotonics overall* (count)			
N	2	0	15
Mean (SD)	2.0 (1.4)		2.1 (0.8)
Median (IQR)	2.0 (1.0 - 3.0)		2.0 (2.0 - 2.0)
Min ; Max	1 ; 3		1 ; 4
Colloids from delivery to time0 (mL)			
N	2	0	11
Mean (SD)	500.0 (0.0)		1272.7 (684.2)
Median (IQR)	500.0 (500.0 - 500.0)		1000.0 (500.0 - 2000.0)
Min ; Max	500 ; 500		500 ; 2500
Colloids from time0 until 24 hours after time0 (mL)			
N	2	0	2
Mean (SD)	500.0 (0.0)		500.0 (0.0)
Median (IQR)	500.0 (500.0 - 500.0)		500.0 (500.0 - 500.0)
Min ; Max	500 ; 500		500 ; 500

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Concomitant medications - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	After first invasive procedure	Missing
Other uterotonics from time0 until 24 hours after time0 (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Other uterotonics overall* (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Colloids from delivery to time0 (mL)		
N	1	0
Mean (SD)	1500.0 (NE)	
Median (IQR)	1500.0 (1500.0 - 1500.0)	
Min ; Max	1500 ; 1500	
Colloids from time0 until 24 hours after time0 (mL)		
N	1	0
Mean (SD)	1000.0 (NE)	
Median (IQR)	1000.0 (1000.0 - 1000.0)	
Min ; Max	1000 ; 1000	

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	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
Colloids overall* (mL)			
N	2	0	12
Mean (SD)	1000.0 (0.0)		1250.0 (690.8)
Median (IQR)	1000.0 (1000.0 - 1000.0)		1250.0 (500.0 - 1750.0)
Min ; Max	1000 ; 1000		500 ; 2500
Crystalloids from delivery to time0 (mL)			
N	1	0	13
Mean (SD)	1200.0 (NE)		1869.2 (1170.0)
Median (IQR)	1200.0 (1200.0 - 1200.0)		1500.0 (1000.0 - 2500.0)
Min ; Max	1200 ; 1200		500 ; 4500
Crystalloids from time0 until 24 hours after time0 (mL)			
N	1	0	11
Mean (SD)	2500.0 (NE)		1581.8 (712.8)
Median (IQR)	2500.0 (2500.0 - 2500.0)		1250.0 (1000.0 - 2000.0)
Min ; Max	2500 ; 2500		1000 ; 3000
Crystalloids overall* (mL)			
N	1	0	14
Mean (SD)	3700.0 (NE)		2296.4 (1239.8)
Median (IQR)	3700.0 (3700.0 - 3700.0)		2125.0 (1500.0 - 3300.0)
Min ; Max	3700 ; 3700		500 ; 4500

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	After first invasive procedure	Missing
Colloids overall* (mL)		
N	1	0
Mean (SD)	2500.0 (NE)	
Median (IQR)	2500.0 (2500.0 - 2500.0)	
Min ; Max	2500 ; 2500	
Crystalloids from delivery to time0 (mL)		
N	1	0
Mean (SD)	500.0 (NE)	
Median (IQR)	500.0 (500.0 - 500.0)	
Min ; Max	500 ; 500	
Crystalloids from time0 until 24 hours after time0 (mL)		
N	1	0
Mean (SD)	1300.0 (NE)	
Median (IQR)	1300.0 (1300.0 - 1300.0)	
Min ; Max	1300 ; 1300	
Crystalloids overall* (mL)		
N	1	0
Mean (SD)	1800.0 (NE)	
Median (IQR)	1800.0 (1800.0 - 1800.0)	
Min ; Max	1800 ; 1800	

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	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
Red blood cells from delivery to time0 (count)			
N	2	0	13
Mean (SD)	2.5 (0.7)		4.5 (3.1)
Median (IQR)	2.5 (2.0 - 3.0)		4.0 (2.0 - 6.0)
Min ; Max	2 ; 3		1 ; 10
Red blood cells from time0 until 24 hours after time0 (count)			
N	2	0	12
Mean (SD)	10.0 (1.4)		6.8 (5.6)
Median (IQR)	10.0 (9.0 - 11.0)		4.5 (3.0 - 9.0)
Min ; Max	9 ; 11		1 ; 20
Red blood cells overall* (count)			
N	2	0	15
Mean (SD)	12.5 (2.1)		9.2 (7.4)
Median (IQR)	12.5 (11.0 - 14.0)		8.0 (2.0 - 11.0)
Min ; Max	11 ; 14		1 ; 29

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	After first invasive procedure	Missing
Red blood cells from delivery to time0 (count)		
N	1	0
Mean (SD)	6.0 (NE)	
Median (IQR)	6.0 (6.0 - 6.0)	
Min ; Max	6 ; 6	
Red blood cells from time0 until 24 hours after time0 (count)		
N	1	0
Mean (SD)	6.0 (NE)	
Median (IQR)	6.0 (6.0 - 6.0)	
Min ; Max	6 ; 6	
Red blood cells overall* (count)		
N	1	0
Mean (SD)	12.0 (NE)	
Median (IQR)	12.0 (12.0 - 12.0)	
Min ; Max	12 ; 12	

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	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
Red blood cells from delivery to time0 (mL)			
N	2	0	13
Mean (SD)	687.5 (194.5)		1226.9 (852.2)
Median (IQR)	687.5 (550.0 - 825.0)		1100.0 (550.0 - 1650.0)
Min ; Max	550 ; 825		275 ; 2750
Red blood cells from time0 until 24 hours after time0 (mL)			
N	2	0	12
Mean (SD)	2750.0 (388.9)		1856.3 (1533.9)
Median (IQR)	2750.0 (2475.0 - 3025.0)		1237.5 (825.0 - 2475.0)
Min ; Max	2475 ; 3025		275 ; 5500
Red blood cells overall* (mL)			
N	2	0	15
Mean (SD)	3437.5 (583.4)		2530.0 (2021.4)
Median (IQR)	3437.5 (3025.0 - 3850.0)		2200.0 (550.0 - 3025.0)
Min ; Max	3025 ; 3850		275 ; 7975

PS: Propensity score, N: Number of patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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	After first invasive procedure	Missing
Red blood cells from delivery to time0 (mL)		
N	1	0
Mean (SD)	1650.0 (NE)	
Median (IQR)	1650.0 (1650.0 - 1650.0)	
Min ; Max	1650 ; 1650	
Red blood cells from time0 until 24 hours after time0 (mL)		
N	1	0
Mean (SD)	1650.0 (NE)	
Median (IQR)	1650.0 (1650.0 - 1650.0)	
Min ; Max	1650 ; 1650	
Red blood cells overall* (mL)		
N	1	0
Mean (SD)	3300.0 (NE)	
Median (IQR)	3300.0 (3300.0 - 3300.0)	
Min ; Max	3300 ; 3300	

PS: Propensity score, N: Number of patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
FFP transfusion from delivery to time0 (count)			
N	2	0	11
Mean (SD)	2.5 (0.7)		4.7 (3.3)
Median (IQR)	2.5 (2.0 - 3.0)		4.0 (2.0 - 9.0)
Min ; Max	2 ; 3		1 ; 10
FFP transfusion from time0 until 24 hours after time0 (count)			
N	2	0	14
Mean (SD)	7.0 (1.4)		5.9 (6.5)
Median (IQR)	7.0 (6.0 - 8.0)		3.5 (2.0 - 7.0)
Min ; Max	6 ; 8		1 ; 23
FFP transfusion overall* (count)			
N	2	0	15
Mean (SD)	9.5 (2.1)		8.7 (7.8)
Median (IQR)	9.5 (8.0 - 11.0)		7.0 (4.0 - 10.0)
Min ; Max	8 ; 11		1 ; 32

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	After first invasive procedure	Missing
FFP transfusion from delivery to time0 (count)		
N	1	0
Mean (SD)	4.0 (NE)	
Median (IQR)	4.0 (4.0 - 4.0)	
Min ; Max	4 ; 4	
FFP transfusion from time0 until 24 hours after time0 (count)		
N	1	0
Mean (SD)	4.0 (NE)	
Median (IQR)	4.0 (4.0 - 4.0)	
Min ; Max	4 ; 4	
FFP transfusion overall* (count)		
N	1	0
Mean (SD)	8.0 (NE)	
Median (IQR)	8.0 (8.0 - 8.0)	
Min ; Max	8 ; 8	

PS: Propensity score, N: Number of patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
FFP transfusion from delivery to time0 (mL)			
N	2	0	11
Mean (SD)	700.0 (198.0)		1323.6 (920.9)
Median (IQR)	700.0 (560.0 - 840.0)		1120.0 (560.0 - 2520.0)
Min ; Max	560 ; 840		280 ; 2800
FFP transfusion from time0 until 24 hours after time0 (mL)			
N	2	0	14
Mean (SD)	1960.0 (396.0)		1640.0 (1824.1)
Median (IQR)	1960.0 (1680.0 - 2240.0)		980.0 (560.0 - 1960.0)
Min ; Max	1680 ; 2240		280 ; 6440
FFP transfusion overall* (mL)			
N	2	0	15
Mean (SD)	2660.0 (594.0)		2445.3 (2190.6)
Median (IQR)	2660.0 (2240.0 - 3080.0)		1960.0 (1120.0 - 2800.0)
Min ; Max	2240 ; 3080		280 ; 8960

PS: Propensity score, N: Number of patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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	After first invasive procedure	Missing
FFP transfusion from delivery to time0 (mL)		
N	1	0
Mean (SD)	1120.0 (NE)	
Median (IQR)	1120.0 (1120.0 - 1120.0)	
Min ; Max	1120 ; 1120	
FFP transfusion from time0 until 24 hours after time0 (mL)		
N	1	0
Mean (SD)	1120.0 (NE)	
Median (IQR)	1120.0 (1120.0 - 1120.0)	
Min ; Max	1120 ; 1120	
FFP transfusion overall* (mL)		
N	1	0
Mean (SD)	2240.0 (NE)	
Median (IQR)	2240.0 (2240.0 - 2240.0)	
Min ; Max	2240 ; 2240	

PS: Propensity score, N: Number of patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
1.0 Platelets from delivery to time0 (count)			
N	0	0	4
Mean (SD)			1.0 (0.0)
Median (IQR)			1.0 (1.0 - 1.0)
Min ; Max			1 ; 1
Platelets from time0 until 24 hours after time0 (count)			
N	2	0	5
Mean (SD)	1.5 (0.7)		1.6 (0.9)
Median (IQR)	1.5 (1.0 - 2.0)		1.0 (1.0 - 2.0)
Min ; Max	1 ; 2		1 ; 3
Platelets overall* (count)			
N	2	0	7
Mean (SD)	1.5 (0.7)		1.6 (1.0)
Median (IQR)	1.5 (1.0 - 2.0)		1.0 (1.0 - 3.0)
Min ; Max	1 ; 2		1 ; 3

PS: Propensity score, N: Number of patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Concomitant medications - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	After first invasive procedure	Missing
Platelets from delivery to time0 (count)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Platelets from time0 until 24 hours after time0 (count)		
N	1	0
Mean (SD)	1.0 (NE)	
Median (IQR)	1.0 (1.0 - 1.0)	
Min ; Max	1 ; 1	
Platelets overall* (count)		
N	1	0
Mean (SD)	1.0 (NE)	
Median (IQR)	1.0 (1.0 - 1.0)	
Min ; Max	1 ; 1	

PS: Propensity score, N: Number of patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
1.0 Platelets from delivery to time0 (mL)			
N	0	0	4
Mean (SD)			125.0 (0.0)
Median (IQR)			125.0 (125.0 - 125.0)
Min ; Max			125 ; 125
Platelets from time0 until 24 hours after time0 (mL)			
N	2	0	5
Mean (SD)	187.5 (88.4)		200.0 (111.8)
Median (IQR)	187.5 (125.0 - 250.0)		125.0 (125.0 - 250.0)
Min ; Max	125 ; 250		125 ; 375
Platelets overall* (mL)			
N	2	0	7
Mean (SD)	187.5 (88.4)		196.4 (122.0)
Median (IQR)	187.5 (125.0 - 250.0)		125.0 (125.0 - 375.0)
Min ; Max	125 ; 250		125 ; 375

PS: Propensity score, N: Number of patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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	After first invasive procedure	Missing
Platelets from delivery to time0 (mL)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Platelets from time0 until 24 hours after time0 (mL)		
N	1	0
Mean (SD)	125.0 (NE)	
Median (IQR)	125.0 (125.0 - 125.0)	
Min ; Max	125 ; 125	
Platelets overall* (mL)		
N	1	0
Mean (SD)	125.0 (NE)	
Median (IQR)	125.0 (125.0 - 125.0)	
Min ; Max	125 ; 125	

PS: Propensity score, N: Number of patients, %: Percentage of patients., SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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14.1.19 Concomitant medications - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Number of patients	4	14
1.0 Tranexamic acid from delivery to time0, N (%)		
Yes	1 (25.0)	9 (64.3)
No	3 (75.0)	5 (35.7)
Tranexamic acid from time0 until 24 hours after time0, N (%)		
Yes	2 (50.0)	1 (7.1)
No	2 (50.0)	13 (92.9)
Tranexamic acid overall*, N (%)		
Yes	3 (75.0)	10 (71.4)
No	1 (25.0)	4 (28.6)
Fibrinogen from delivery to time0, N (%)		
Yes	2 (50.0)	4 (28.6)
No	2 (50.0)	10 (71.4)
Fibrinogen from time0 until 24 hours after time0, N (%)		
Yes	2 (50.0)	1 (7.1)
No	2 (50.0)	13 (92.9)

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Fibrinogen overall*, N (%)		
Yes	3 (75.0)	5 (35.7)
No	1 (25.0)	9 (64.3)
1.0 Oxytocin from delivery to time0 (count)		
N	3	13
Mean (SD)	2.0 (1.0)	2.3 (1.4)
Median (IQR)	2.0 (1.0 - 3.0)	2.0 (1.0 - 3.0)
Min ; Max	1 ; 3	1 ; 6
Oxytocin from time0 until 24 hours after time0 (count)		
N	3	6
Mean (SD)	1.0 (0.0)	1.2 (0.4)
Median (IQR)	1.0 (1.0 - 1.0)	1.0 (1.0 - 1.0)
Min ; Max	1 ; 1	1 ; 2
Oxytocin overall* (count)		
N	3	13
Mean (SD)	2.0 (1.0)	2.7 (1.4)
Median (IQR)	2.0 (1.0 - 3.0)	3.0 (2.0 - 3.0)
Min ; Max	1 ; 3	1 ; 6
Other uterotonics from delivery to time0 (count)		
N	2	13
Mean (SD)	2.0 (0.0)	1.6 (0.9)
Median (IQR)	2.0 (2.0 - 2.0)	1.0 (1.0 - 2.0)
Min ; Max	2 ; 2	1 ; 4

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Other uterotonics from time0 until 24 hours after time0 (count)		
N	3	6
Mean (SD)	1.7 (0.6)	1.2 (0.4)
Median (IQR)	2.0 (1.0 - 2.0)	1.0 (1.0 - 1.0)
Min ; Max	1 ; 2	1 ; 2
Other uterotonics overall* (count)		
N	4	13
Mean (SD)	2.0 (0.0)	2.1 (1.0)
Median (IQR)	2.0 (2.0 - 2.0)	2.0 (1.0 - 3.0)
Min ; Max	2 ; 2	1 ; 4
Colloids from delivery to time0 (mL)		
N	1	13
Mean (SD)	2000.0 (NE)	1115.4 (650.4)
Median (IQR)	2000.0 (2000.0 - 2000.0)	1000.0 (500.0 - 1500.0)
Min ; Max	2000 ; 2000	500 ; 2500
Colloids from time0 until 24 hours after time0 (mL)		
N	1	4
Mean (SD)	500.0 (NE)	625.0 (250.0)
Median (IQR)	500.0 (500.0 - 500.0)	500.0 (500.0 - 750.0)
Min ; Max	500 ; 500	500 ; 1000

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Colloids overall* (mL)		
N	2	13
Mean (SD)	1250.0 (1060.7)	1307.7 (693.4)
Median (IQR)	1250.0 (500.0 - 2000.0)	1000.0 (1000.0 - 1500.0)
Min ; Max	500 ; 2000	500 ; 2500
Crystalloids from delivery to time0 (mL)		
N	2	13
Mean (SD)	1900.0 (1838.5)	1707.7 (1119.1)
Median (IQR)	1900.0 (600.0 - 3200.0)	1500.0 (1000.0 - 2000.0)
Min ; Max	600 ; 3200	500 ; 4500
Crystalloids from time0 until 24 hours after time0 (mL)		
N	3	10
Mean (SD)	1316.7 (388.4)	1725.0 (766.4)
Median (IQR)	1200.0 (1000.0 - 1750.0)	1400.0 (1000.0 - 2500.0)
Min ; Max	1000 ; 1750	1000 ; 3000
Crystalloids overall* (mL)		
N	3	13
Mean (SD)	1466.7 (1588.5)	2557.7 (1087.8)
Median (IQR)	600.0 (500.0 - 3300.0)	2250.0 (1800.0 - 3500.0)
Min ; Max	500 ; 3300	1000 ; 4500

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Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Red blood cells from delivery to time0 (count)		
N	2	14
Mean (SD)	2.5 (2.1)	4.6 (3.0)
Median (IQR)	2.5 (1.0 - 4.0)	4.5 (2.0 - 6.0)
Min ; Max	1 ; 4	1 ; 10
Red blood cells from time0 until 24 hours after time0 (count)		
N	4	11
Mean (SD)	4.0 (3.2)	8.3 (5.3)
Median (IQR)	3.5 (1.5 - 6.5)	7.0 (4.0 - 11.0)
Min ; Max	1 ; 8	3 ; 20
Red blood cells overall* (count)		
N	4	14
Mean (SD)	5.0 (4.1)	11.1 (6.9)
Median (IQR)	5.0 (1.5 - 8.5)	11.0 (8.0 - 14.0)
Min ; Max	1 ; 9	2 ; 29

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Concomitant medications - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Red blood cells from delivery to time0 (mL)		
N	2	14
Mean (SD)	687.5 (583.4)	1257.1 (812.3)
Median (IQR)	687.5 (275.0 - 1100.0)	1237.5 (550.0 - 1650.0)
Min ; Max	275 ; 1100	275 ; 2750
Red blood cells from time0 until 24 hours after time0 (mL)		
N	4	11
Mean (SD)	1100.0 (869.6)	2275.0 (1455.6)
Median (IQR)	962.5 (412.5 - 1787.5)	1925.0 (1100.0 - 3025.0)
Min ; Max	275 ; 2200	825 ; 5500
Red blood cells overall* (mL)		
N	4	14
Mean (SD)	1375.0 (1122.7)	3044.6 (1900.6)
Median (IQR)	1375.0 (412.5 - 2337.5)	3025.0 (2200.0 - 3850.0)
Min ; Max	275 ; 2475	550 ; 7975

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
FFP transfusion from delivery to time0 (count)		
N	1	13
Mean (SD)	6.0 (NE)	4.2 (3.1)
Median (IQR)	6.0 (6.0 - 6.0)	3.0 (2.0 - 4.0)
Min ; Max	6 ; 6	1 ; 10
FFP transfusion from time0 until 24 hours after time0 (count)		
N	4	13
Mean (SD)	4.8 (2.5)	6.2 (6.7)
Median (IQR)	4.5 (3.0 - 6.5)	4.0 (2.0 - 7.0)
Min ; Max	2 ; 8	1 ; 23
FFP transfusion overall* (count)		
N	4	14
Mean (SD)	5.5 (3.7)	9.7 (7.7)
Median (IQR)	6.0 (2.5 - 8.5)	8.0 (5.0 - 11.0)
Min ; Max	1 ; 9	2 ; 32

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
FFP transfusion from delivery to time0 (mL)		
N	1	13
Mean (SD)	1680.0 (NE)	1184.6 (864.2)
Median (IQR)	1680.0 (1680.0 - 1680.0)	840.0 (560.0 - 1120.0)
Min ; Max	1680 ; 1680	280 ; 2800
FFP transfusion from time0 until 24 hours after time0 (mL)		
N	4	13
Mean (SD)	1330.0 (700.0)	1744.6 (1868.4)
Median (IQR)	1260.0 (840.0 - 1820.0)	1120.0 (560.0 - 1960.0)
Min ; Max	560 ; 2240	280 ; 6440
FFP transfusion overall* (mL)		
N	4	14
Mean (SD)	1540.0 (1035.1)	2720.0 (2150.5)
Median (IQR)	1680.0 (700.0 - 2380.0)	2240.0 (1400.0 - 3080.0)
Min ; Max	280 ; 2520	560 ; 8960

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Platelets from delivery to time0 (count)		
N	0	4
Mean (SD)		1.0 (0.0)
Median (IQR)		1.0 (1.0 - 1.0)
Min ; Max		1 ; 1
Platelets from time0 until 24 hours after time0 (count)		
N	2	6
Mean (SD)	1.0 (0.0)	1.7 (0.8)
Median (IQR)	1.0 (1.0 - 1.0)	1.5 (1.0 - 2.0)
Min ; Max	1 ; 1	1 ; 3
Platelets overall* (count)		
N	1	9
Mean (SD)	1.0 (NE)	1.6 (0.9)
Median (IQR)	1.0 (1.0 - 1.0)	1.0 (1.0 - 2.0)
Min ; Max	1 ; 1	1 ; 3

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Platelets from delivery to time0 (mL)		
N	0	4
Mean (SD)		125.0 (0.0)
Median (IQR)		125.0 (125.0 - 125.0)
Min ; Max		125 ; 125
Platelets from time0 until 24 hours after time0 (mL)		
N	2	6
Mean (SD)	125.0 (0.0)	208.3 (102.1)
Median (IQR)	125.0 (125.0 - 125.0)	187.5 (125.0 - 250.0)
Min ; Max	125 ; 125	125 ; 375
Platelets overall* (mL)		
N	1	9
Mean (SD)	125.0 (NE)	194.4 (110.2)
Median (IQR)	125.0 (125.0 - 125.0)	125.0 (125.0 - 250.0)
Min ; Max	125 ; 125	125 ; 375

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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14.1.20 Concomitant medications - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Number of patients	2	16	0
Tranexamic acid from delivery to time0, N (%)			
Yes	1 (50.0)	9 (56.3)	0
No	1 (50.0)	7 (43.8)	0
Tranexamic acid from time0 until 24 hours after time0, N (%)			
Yes	0	3 (18.8)	0
No	2 (100.0)	13 (81.3)	0
Tranexamic acid overall*, N (%)			
Yes	1 (50.0)	12 (75.0)	0
No	1 (50.0)	4 (25.0)	0
Fibrinogen from delivery to time0, N (%)			
Yes	1 (50.0)	5 (31.3)	0
No	1 (50.0)	11 (68.8)	0
Fibrinogen from time0 until 24 hours after time0, N (%)			
Yes	1 (50.0)	2 (12.5)	0
No	1 (50.0)	14 (87.5)	0

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Fibrinogen overall*, N (%)			
Yes	1 (50.0)	7 (43.8)	0
No	1 (50.0)	9 (56.3)	0
1.0 Oxytocin from delivery to time0 (count)			
N	2	14	0
Mean (SD)	3.0 (0.0)	2.1 (1.4)	
Median (IQR)	3.0 (3.0 - 3.0)	2.0 (1.0 - 2.0)	
Min ; Max	3 ; 3	1 ; 6	
Oxytocin from time0 until 24 hours after time0 (count)			
N	2	7	0
Mean (SD)	1.0 (0.0)	1.1 (0.4)	
Median (IQR)	1.0 (1.0 - 1.0)	1.0 (1.0 - 1.0)	
Min ; Max	1 ; 1	1 ; 2	
Oxytocin overall* (count)			
N	2	14	0
Mean (SD)	3.5 (0.7)	2.4 (1.4)	
Median (IQR)	3.5 (3.0 - 4.0)	2.0 (1.0 - 3.0)	
Min ; Max	3 ; 4	1 ; 6	
Other uterotonics from delivery to time0 (count)			
N	0	15	0
Mean (SD)		1.7 (0.8)	
Median (IQR)		2.0 (1.0 - 2.0)	
Min ; Max		1 ; 4	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Other uterotonics from time0 until 24 hours after time0 (count)			
N	1	8	0
Mean (SD)	2.0 (NE)	1.3 (0.5)	
Median (IQR)	2.0 (2.0 - 2.0)	1.0 (1.0 - 1.5)	
Min ; Max	2 ; 2	1 ; 2	
Other uterotonics overall* (count)			
N	1	16	0
Mean (SD)	2.0 (NE)	2.1 (0.9)	
Median (IQR)	2.0 (2.0 - 2.0)	2.0 (1.5 - 2.5)	
Min ; Max	2 ; 2	1 ; 4	
Colloids from delivery to time0 (mL)			
N	2	12	0
Mean (SD)	1750.0 (353.6)	1083.3 (668.6)	
Median (IQR)	1750.0 (1500.0 - 2000.0)	1000.0 (500.0 - 1500.0)	
Min ; Max	1500 ; 2000	500 ; 2500	
Colloids from time0 until 24 hours after time0 (mL)			
N	1	4	0
Mean (SD)	1000.0 (NE)	500.0 (0.0)	
Median (IQR)	1000.0 (1000.0 - 1000.0)	500.0 (500.0 - 500.0)	
Min ; Max	1000 ; 1000	500 ; 500	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Colloids overall* (mL)			
N	2	13	0
Mean (SD)	2250.0 (353.6)	1153.8 (625.3)	
Median (IQR)	2250.0 (2000.0 - 2500.0)	1000.0 (500.0 - 1500.0)	
Min ; Max	2000 ; 2500	500 ; 2500	
Crystalloids from delivery to time0 (mL)			
N	2	13	0
Mean (SD)	1850.0 (1909.2)	1715.4 (1110.4)	
Median (IQR)	1850.0 (500.0 - 3200.0)	1500.0 (1000.0 - 2000.0)	
Min ; Max	500 ; 3200	500 ; 4500	
Crystalloids from time0 until 24 hours after time0 (mL)			
N	2	11	0
Mean (SD)	1250.0 (70.7)	1700.0 (750.0)	
Median (IQR)	1250.0 (1200.0 - 1300.0)	1500.0 (1000.0 - 2500.0)	
Min ; Max	1200 ; 1300	1000 ; 3000	
Crystalloids overall* (mL)			
N	2	14	0
Mean (SD)	2550.0 (1060.7)	2325.0 (1269.0)	
Median (IQR)	2550.0 (1800.0 - 3300.0)	2125.0 (1500.0 - 3500.0)	
Min ; Max	1800 ; 3300	500 ; 4500	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Red blood cells from delivery to time0 (count)			
N	2	14	0
Mean (SD)	5.0 (1.4)	4.2 (3.1)	
Median (IQR)	5.0 (4.0 - 6.0)	3.5 (2.0 - 6.0)	
Min ; Max	4 ; 6	1 ; 10	
Red blood cells from time0 until 24 hours after time0 (count)			
N	2	13	0
Mean (SD)	5.5 (0.7)	7.4 (5.5)	
Median (IQR)	5.5 (5.0 - 6.0)	7.0 (3.0 - 10.0)	
Min ; Max	5 ; 6	1 ; 20	
Red blood cells overall* (count)			
N	2	16	0
Mean (SD)	10.5 (2.1)	9.6 (7.2)	
Median (IQR)	10.5 (9.0 - 12.0)	8.0 (4.0 - 12.5)	
Min ; Max	9 ; 12	1 ; 29	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Red blood cells from delivery to time0 (mL)			
N	2	14	0
Mean (SD)	1375.0 (388.9)	1158.9 (843.7)	
Median (IQR)	1375.0 (1100.0 - 1650.0)	962.5 (550.0 - 1650.0)	
Min ; Max	1100 ; 1650	275 ; 2750	
Red blood cells from time0 until 24 hours after time0 (mL)			
N	2	13	0
Mean (SD)	1512.5 (194.5)	2030.8 (1500.1)	
Median (IQR)	1512.5 (1375.0 - 1650.0)	1925.0 (825.0 - 2750.0)	
Min ; Max	1375 ; 1650	275 ; 5500	
Red blood cells overall* (mL)			
N	2	16	0
Mean (SD)	2887.5 (583.4)	2646.9 (1982.7)	
Median (IQR)	2887.5 (2475.0 - 3300.0)	2200.0 (1100.0 - 3437.5)	
Min ; Max	2475 ; 3300	275 ; 7975	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
FFP transfusion from delivery to time0 (count)			
N	2	12	0
Mean (SD)	5.0 (1.4)	4.3 (3.2)	
Median (IQR)	5.0 (4.0 - 6.0)	3.0 (2.0 - 6.5)	
Min ; Max	4 ; 6	1 ; 10	
FFP transfusion from time0 until 24 hours after time0 (count)			
N	2	15	0
Mean (SD)	4.5 (0.7)	6.1 (6.3)	
Median (IQR)	4.5 (4.0 - 5.0)	4.0 (2.0 - 8.0)	
Min ; Max	4 ; 5	1 ; 23	
FFP transfusion overall* (count)			
N	2	16	0
Mean (SD)	8.5 (0.7)	8.8 (7.6)	
Median (IQR)	8.5 (8.0 - 9.0)	7.5 (4.0 - 10.5)	
Min ; Max	8 ; 9	1 ; 32	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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	<60 µg/kg	60-90 µg/kg	>90 µg/kg
FFP transfusion from delivery to time0 (mL)			
N	2	12	0
Mean (SD)	1400.0 (396.0)	1190.0 (902.4)	
Median (IQR)	1400.0 (1120.0 - 1680.0)	840.0 (560.0 - 1820.0)	
Min ; Max	1120 ; 1680	280 ; 2800	
FFP transfusion from time0 until 24 hours after time0 (mL)			
N	2	15	0
Mean (SD)	1260.0 (198.0)	1698.7 (1762.8)	
Median (IQR)	1260.0 (1120.0 - 1400.0)	1120.0 (560.0 - 2240.0)	
Min ; Max	1120 ; 1400	280 ; 6440	
FFP transfusion overall* (mL)			
N	2	16	0
Mean (SD)	2380.0 (198.0)	2467.5 (2123.1)	
Median (IQR)	2380.0 (2240.0 - 2520.0)	2100.0 (1120.0 - 2940.0)	
Min ; Max	2240 ; 2520	280 ; 8960	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Platelets from delivery to time0 (count)			
N	0	4	0
Mean (SD)		1.0 (0.0)	
Median (IQR)		1.0 (1.0 - 1.0)	
Min ; Max		1 ; 1	
Platelets from time0 until 24 hours after time0 (count)			
N	2	6	0
Mean (SD)	1.0 (0.0)	1.7 (0.8)	
Median (IQR)	1.0 (1.0 - 1.0)	1.5 (1.0 - 2.0)	
Min ; Max	1 ; 1	1 ; 3	
Platelets overall* (count)			
N	2	8	0
Mean (SD)	1.0 (0.0)	1.6 (0.9)	
Median (IQR)	1.0 (1.0 - 1.0)	1.0 (1.0 - 2.5)	
Min ; Max	1 ; 1	1 ; 3	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medications - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Platelets from delivery to time0 (mL)			
N	0	4	0
Mean (SD)		125.0 (0.0)	
Median (IQR)		125.0 (125.0 - 125.0)	
Min ; Max		125 ; 125	
Platelets from time0 until 24 hours after time0 (mL)			
N	2	6	0
Mean (SD)	125.0 (0.0)	208.3 (102.1)	
Median (IQR)	125.0 (125.0 - 125.0)	187.5 (125.0 - 250.0)	
Min ; Max	125 ; 125	125 ; 375	
Platelets overall* (mL)			
N	2	8	0
Mean (SD)	125.0 (0.0)	203.1 (114.5)	
Median (IQR)	125.0 (125.0 - 125.0)	125.0 (125.0 - 312.5)	
Min ; Max	125 ; 125	125 ; 375	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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14.1.21 Concomitant medication - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	2	11	5	0
Tranexamic acid from delivery to time0, N (%)				
Yes	0	7 (63.6)	3 (60.0)	0
No	2 (100.0)	4 (36.4)	2 (40.0)	0
Tranexamic acid from time0 until 24 hours after time0, N (%)				
Yes	2 (100.0)	1 (9.1)	0	0
No	0	10 (90.9)	5 (100.0)	0
Tranexamic acid overall*, N (%)				
Yes	2 (100.0)	8 (72.7)	3 (60.0)	0
No	0	3 (27.3)	2 (40.0)	0
Fibrinogen from delivery to time0, N (%)				
Yes	0	4 (36.4)	2 (40.0)	0
No	2 (100.0)	7 (63.6)	3 (60.0)	0
Fibrinogen from time0 until 24 hours after time0, N (%)				
Yes	1 (50.0)	1 (9.1)	1 (20.0)	0
No	1 (50.0)	10 (90.9)	4 (80.0)	0

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Fibrinogen overall*, N (%)				
Yes	1 (50.0)	4 (36.4)	3 (60.0)	0
No	1 (50.0)	7 (63.6)	2 (40.0)	0
Oxytocin from delivery to time0 (count)				
N	0	11	5	0
Mean (SD)		1.9 (0.8)	3.0 (2.0)	
Median (IQR)		2.0 (1.0 - 3.0)	2.0 (2.0 - 4.0)	
Min ; Max		1 ; 3	1 ; 6	
Oxytocin from time0 until 24 hours after time0 (count)				
N	1	5	3	0
Mean (SD)	1.0 (NE)	1.0 (0.0)	1.3 (0.6)	
Median (IQR)	1.0 (1.0 - 1.0)	1.0 (1.0 - 1.0)	1.0 (1.0 - 2.0)	
Min ; Max	1 ; 1	1 ; 1	1 ; 2	
Oxytocin overall* (count)				
N	0	11	5	0
Mean (SD)		2.0 (1.0)	3.8 (1.3)	
Median (IQR)		2.0 (1.0 - 3.0)	3.0 (3.0 - 4.0)	
Min ; Max		1 ; 4	3 ; 6	
Other uterotonics from delivery to time0 (count)				
N	2	8	5	0
Mean (SD)	1.5 (0.7)	1.5 (0.5)	2.0 (1.2)	
Median (IQR)	1.5 (1.0 - 2.0)	1.5 (1.0 - 2.0)	2.0 (1.0 - 2.0)	
Min ; Max	1 ; 2	1 ; 2	1 ; 4	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Other uterotonics from time0 until 24 hours after time0 (count)				
N	1	5	3	0
Mean (SD)	1.0 (NE)	1.6 (0.5)	1.0 (0.0)	
Median (IQR)	1.0 (1.0 - 1.0)	2.0 (1.0 - 2.0)	1.0 (1.0 - 1.0)	
Min ; Max	1 ; 1	1 ; 2	1 ; 1	
Other uterotonics overall* (count)				
N	2	10	5	0
Mean (SD)	1.5 (0.7)	1.9 (0.6)	2.6 (1.1)	
Median (IQR)	1.5 (1.0 - 2.0)	2.0 (2.0 - 2.0)	3.0 (2.0 - 3.0)	
Min ; Max	1 ; 2	1 ; 3	1 ; 4	
Colloids from delivery to time0 (mL)				
N	1	8	5	0
Mean (SD)	500.0 (NE)	1375.0 (640.9)	1000.0 (707.1)	
Median (IQR)	500.0 (500.0 - 500.0)	1250.0 (1000.0 - 1750.0)	500.0 (500.0 - 1500.0)	
Min ; Max	500 ; 500	500 ; 2500	500 ; 2000	
Colloids from time0 until 24 hours after time0 (mL)				
N	2	2	1	0
Mean (SD)	500.0 (0.0)	750.0 (353.6)	500.0 (NE)	
Median (IQR)	500.0 (500.0 - 500.0)	750.0 (500.0 - 1000.0)	500.0 (500.0 - 500.0)	
Min ; Max	500 ; 500	500 ; 1000	500 ; 500	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Colloids overall* (mL)				
N	2	8	5	0
Mean (SD)	750.0 (353.6)	1562.5 (728.9)	1100.0 (651.9)	
Median (IQR)	750.0 (500.0 - 1000.0)	1500.0 (1000.0 - 2250.0)	1000.0 (500.0 - 1500.0)	
Min ; Max	500 ; 1000	500 ; 2500	500 ; 2000	
Crystalloids from delivery to time0 (mL)				
N	0	10	5	0
Mean (SD)		1530.0 (909.3)	2140.0 (1564.6)	
Median (IQR)		1500.0 (600.0 - 2000.0)	1200.0 (1000.0 - 3000.0)	
Min ; Max		500 ; 3200	1000 ; 4500	
Crystalloids from time0 until 24 hours after time0 (mL)				
N	1	10	2	0
Mean (SD)	1750.0 (NE)	1395.0 (555.0)	2750.0 (353.6)	
Median (IQR)	1750.0 (1750.0 - 1750.0)	1225.0 (1000.0 - 1500.0)	2750.0 (2500.0 - 3000.0)	
Min ; Max	1750 ; 1750	1000 ; 2700	2500 ; 3000	
Crystalloids overall* (mL)				
N	1	10	5	0
Mean (SD)	500.0 (NE)	2095.0 (860.4)	3240.0 (1364.9)	
Median (IQR)	500.0 (500.0 - 500.0)	2000.0 (1500.0 - 2500.0)	3700.0 (3000.0 - 4000.0)	
Min ; Max	500 ; 500	600 ; 3500	1000 ; 4500	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Red blood cells from delivery to time0 (count)				
N	1	10	5	0
Mean (SD)	3.0 (NE)	3.7 (2.8)	5.8 (3.2)	
Median (IQR)	3.0 (3.0 - 3.0)	3.0 (1.0 - 6.0)	5.0 (4.0 - 8.0)	
Min ; Max	3 ; 3	1 ; 9	2 ; 10	
Red blood cells from time0 until 24 hours after time0 (count)				
N	2	8	5	0
Mean (SD)	6.5 (6.4)	7.5 (5.8)	6.8 (4.7)	
Median (IQR)	6.5 (2.0 - 11.0)	6.5 (4.0 - 9.0)	4.0 (4.0 - 9.0)	
Min ; Max	2 ; 11	1 ; 20	3 ; 14	
Red blood cells overall* (count)				
N	2	11	5	0
Mean (SD)	7.5 (9.2)	8.8 (7.6)	12.6 (4.2)	
Median (IQR)	7.5 (1.0 - 14.0)	8.0 (2.0 - 11.0)	11.0 (11.0 - 14.0)	
Min ; Max	1 ; 14	2 ; 29	8 ; 19	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Red blood cells from delivery to time0 (mL)				
N	1	10	5	0
Mean (SD)	825.0 (NE)	1017.5 (756.5)	1595.0 (878.3)	
Median (IQR)	825.0 (825.0 - 825.0)	825.0 (275.0 - 1650.0)	1375.0 (1100.0 - 2200.0)	
Min ; Max	825 ; 825	275 ; 2475	550 ; 2750	
Red blood cells from time0 until 24 hours after time0 (mL)				
N	2	8	5	0
Mean (SD)	1787.5 (1750.1)	2062.5 (1590.0)	1870.0 (1281.0)	
Median (IQR)	1787.5 (550.0 - 3025.0)	1787.5 (1100.0 - 2475.0)	1100.0 (1100.0 - 2475.0)	
Min ; Max	550 ; 3025	275 ; 5500	825 ; 3850	
Red blood cells overall* (mL)				
N	2	11	5	0
Mean (SD)	2062.5 (2527.9)	2425.0 (2079.2)	3465.0 (1143.8)	
Median (IQR)	2062.5 (275.0 - 3850.0)	2200.0 (550.0 - 3025.0)	3025.0 (3025.0 - 3850.0)	
Min ; Max	275 ; 3850	550 ; 7975	2200 ; 5225	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
FFP transfusion from delivery to time0 (count)				
N	1	8	5	0
Mean (SD)	3.0 (NE)	3.9 (2.6)	5.4 (3.8)	
Median (IQR)	3.0 (3.0 - 3.0)	3.5 (2.0 - 5.0)	4.0 (2.0 - 9.0)	
Min ; Max	3 ; 3	1 ; 9	2 ; 10	
FFP transfusion from time0 until 24 hours after time0 (count)				
N	2	10	5	0
Mean (SD)	5.0 (4.2)	6.1 (6.4)	5.8 (6.5)	
Median (IQR)	5.0 (2.0 - 8.0)	4.5 (2.0 - 7.0)	3.0 (2.0 - 6.0)	
Min ; Max	2 ; 8	1 ; 23	1 ; 17	
FFP transfusion overall* (count)				
N	2	11	5	0
Mean (SD)	6.0 (7.1)	8.2 (8.2)	11.2 (4.8)	
Median (IQR)	6.0 (1.0 - 11.0)	6.0 (4.0 - 8.0)	10.0 (8.0 - 12.0)	
Min ; Max	1 ; 11	2 ; 32	7 ; 19	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
FFP transfusion from delivery to time0 (mL)				
N	1	8	5	0
Mean (SD)	840.0 (NE)	1085.0 (739.9)	1512.0 (1077.2)	
Median (IQR)	840.0 (840.0 - 840.0)	980.0 (560.0 - 1400.0)	1120.0 (560.0 - 2520.0)	
Min ; Max	840 ; 840	280 ; 2520	560 ; 2800	
FFP transfusion from time0 until 24 hours after time0 (mL)				
N	2	10	5	0
Mean (SD)	1400.0 (1187.9)	1708.0 (1792.6)	1624.0 (1829.7)	
Median (IQR)	1400.0 (560.0 - 2240.0)	1260.0 (560.0 - 1960.0)	840.0 (560.0 - 1680.0)	
Min ; Max	560 ; 2240	280 ; 6440	280 ; 4760	
FFP transfusion overall* (mL)				
N	2	11	5	0
Mean (SD)	1680.0 (1979.9)	2290.9 (2298.1)	3136.0 (1334.0)	
Median (IQR)	1680.0 (280.0 - 3080.0)	1680.0 (1120.0 - 2240.0)	2800.0 (2240.0 - 3360.0)	
Min ; Max	280 ; 3080	560 ; 8960	1960 ; 5320	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Platelets from delivery to time0 (count)				
N	0	2	2	0
Mean (SD)		1.0 (0.0)	1.0 (0.0)	
Median (IQR)		1.0 (1.0 - 1.0)	1.0 (1.0 - 1.0)	
Min ; Max		1 ; 1	1 ; 1	
Platelets from time0 until 24 hours after time0 (count)				
N	1	5	2	0
Mean (SD)	2.0 (NE)	1.2 (0.4)	2.0 (1.4)	
Median (IQR)	2.0 (2.0 - 2.0)	1.0 (1.0 - 1.0)	2.0 (1.0 - 3.0)	
Min ; Max	2 ; 2	1 ; 2	1 ; 3	
Platelets overall* (count)				
N	1	5	4	0
Mean (SD)	2.0 (NE)	1.4 (0.9)	1.5 (1.0)	
Median (IQR)	2.0 (2.0 - 2.0)	1.0 (1.0 - 1.0)	1.0 (1.0 - 2.0)	
Min ; Max	2 ; 2	1 ; 3	1 ; 3	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Platelets from delivery to time0 (mL)				
N	0	2	2	0
Mean (SD)		125.0 (0.0)	125.0 (0.0)	
Median (IQR)		125.0 (125.0 - 125.0)	125.0 (125.0 - 125.0)	
Min ; Max		125 ; 125	125 ; 125	
Platelets from time0 until 24 hours after time0 (mL)				
N	1	5	2	0
Mean (SD)	250.0 (NE)	150.0 (55.9)	250.0 (176.8)	
Median (IQR)	250.0 (250.0 - 250.0)	125.0 (125.0 - 125.0)	250.0 (125.0 - 375.0)	
Min ; Max	250 ; 250	125 ; 250	125 ; 375	
Platelets overall* (mL)				
N	1	5	4	0
Mean (SD)	250.0 (NE)	175.0 (111.8)	187.5 (125.0)	
Median (IQR)	250.0 (250.0 - 250.0)	125.0 (125.0 - 125.0)	125.0 (125.0 - 250.0)	
Min ; Max	250 ; 250	125 ; 375	125 ; 375	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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14.1.22 Concomitant medication - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	1	26	16	0
Number of weighted patients, N	0.3	8.1	9.7	0
Tranexamic acid from delivery to time0, N (%)				
Yes	0	4.4 (54.6)	3.6 (37.1)	0
No	0.3 (100.0)	3.7 (45.4)	6.1 (62.9)	0
Tranexamic acid from time0 until 24 hours after time0, N (%)				
Yes	0.3 (100.0)	2.2 (26.8)	5.5 (56.9)	0
No	0	5.9 (73.2)	4.2 (43.1)	0
Tranexamic acid overall*, N (%)				
Yes	0.3 (100.0)	6.6 (81.4)	7.1 (73.3)	0
No	0	1.5 (18.6)	2.6 (26.7)	0
Fibrinogen from delivery to time0, N (%)				
Yes	0	0.6 (7.2)	2.0 (20.7)	0
No	0.3 (100.0)	7.5 (92.8)	7.7 (79.3)	0
Fibrinogen from time0 until 24 hours after time0, N (%)				
Yes	0.3 (100.0)	1.5 (18.6)	1.8 (19.0)	0
No	0	6.6 (81.4)	7.8 (81.0)	0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Fibrinogen overall*, N (%)				
Yes	0.3 (100.0)	1.8 (22.7)	3.8 (39.7)	0
No	0	6.3 (77.3)	5.8 (60.3)	0
Oxytocin from delivery to time0 (count)				
N	0	6.3	8.9	0
Mean (SD)		2.1 (0.5)	2.2 (1.3)	
Median (IQR)		2.0 (1.0 - 3.0)	2.0 (1.0 - 3.0)	
Min ; Max		1 ; 3	1 ; 6	
Oxytocin from time0 until 24 hours after time0 (count)				
N	0	4.1	4.3	0
Mean (SD)		1.3 (0.3)	1.9 (0.7)	
Median (IQR)		1.0 (1.0 - 2.0)	2.0 (1.0 - 2.0)	
Min ; Max		1 ; 2	1 ; 4	
Oxytocin overall* (count)				
N	0	6.8	9.4	0
Mean (SD)		2.7 (0.9)	2.8 (1.4)	
Median (IQR)		3.0 (1.0 - 3.0)	3.0 (1.0 - 4.0)	
Min ; Max		1 ; 6	1 ; 6	
Other uterotonics from delivery to time0 (count)				
N	0.3	5.0	6.7	0
Mean (SD)	2.0 (NE)	1.6 (0.4)	1.9 (1.0)	
Median (IQR)	2.0 (2.0 - 2.0)	2.0 (1.0 - 2.0)	1.0 (1.0 - 3.0)	
Min ; Max	2 ; 2	1 ; 3	1 ; 4	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Other uterotonics from time0 until 24 hours after time0 (count)				
N	0	2.8	4.0	0
Mean (SD)		1.5 (0.3)	1.3 (0.4)	
Median (IQR)		1.0 (1.0 - 2.0)	1.0 (1.0 - 1.5)	
Min ; Max		1 ; 3	1 ; 3	
Other uterotonics overall* (count)				
N	0.3	6.0	7.2	0
Mean (SD)	2.0 (NE)	1.9 (0.3)	2.5 (0.8)	
Median (IQR)	2.0 (2.0 - 2.0)	2.0 (2.0 - 2.0)	2.0 (2.0 - 3.0)	
Min ; Max	2 ; 2	1 ; 3	1 ; 4	
Colloids from delivery to time0 (mL)				
N	0.3	6.8	8.9	0
Mean (SD)	1000.0 (NE)	1085.4 (364.6)	1238.3 (619.0)	
Median (IQR)	1000.0 (1000.0 - 1000.0)	1000.0 (500.0 - 1500.0)	1000.0 (500.0 - 2000.0)	
Min ; Max	1000 ; 1000	500 ; 2000	500 ; 2500	
Colloids from time0 until 24 hours after time0 (mL)				
N	0.3	3.8	4.8	0
Mean (SD)	500.0 (NE)	630.4 (135.9)	1258.6 (508.5)	
Median (IQR)	500.0 (500.0 - 500.0)	500.0 (500.0 - 1000.0)	1500.0 (500.0 - 1500.0)	
Min ; Max	500 ; 500	500 ; 1000	500 ; 2500	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Colloids overall* (mL)				
N	0.3	7.1	9.4	0
Mean (SD)	1500.0 (NE)	1547.1 (598.6)	1818.6 (771.6)	
Median (IQR)	1500.0 (1500.0 - 1500.0)	1000.0 (500.0 - 2500.0)	2000.0 (1000.0 - 2500.0)	
Min ; Max	1500 ; 1500	500 ; 3500	500 ; 4000	
Crystalloids from delivery to time0 (mL)				
N	0.3	7.3	9.4	0
Mean (SD)	2000.0 (NE)	1532.8 (934.5)	2605.3 (680.8)	
Median (IQR)	2000.0 (2000.0 - 2000.0)	1000.0 (500.0 - 1800.0)	2500.0 (2400.0 - 3100.0)	
Min ; Max	2000 ; 2000	500 ; 7000	500 ; 4100	
Crystalloids from time0 until 24 hours after time0 (mL)				
N	0.3	6.5	8.3	0
Mean (SD)	1000.0 (NE)	1551.9 (420.1)	2381.0 (1324.1)	
Median (IQR)	1000.0 (1000.0 - 1000.0)	1500.0 (1000.0 - 2000.0)	2000.0 (1000.0 - 3000.0)	
Min ; Max	1000 ; 1000	100 ; 3500	300 ; 8000	
Crystalloids overall* (mL)				
N	0.3	7.5	9.7	0
Mean (SD)	3000.0 (NE)	2572.2 (933.4)	4181.9 (971.6)	
Median (IQR)	3000.0 (3000.0 - 3000.0)	2000.0 (1500.0 - 3500.0)	4200.0 (3100.0 - 5250.0)	
Min ; Max	3000 ; 3000	500 ; 7000	2500 ; 6500	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Red blood cells from delivery to time0 (count)				
N	0.3	5.1	8.9	0
Mean (SD)	2.0 (NE)	4.0 (1.5)	4.7 (2.0)	
Median (IQR)	2.0 (2.0 - 2.0)	4.0 (2.0 - 6.0)	4.0 (3.0 - 6.0)	
Min ; Max	2 ; 2	1 ; 8	2 ; 10	
Red blood cells from time0 until 24 hours after time0 (count)				
N	0.3	6.5	9.7	0
Mean (SD)	15.0 (NE)	5.8 (3.1)	9.4 (3.6)	
Median (IQR)	15.0 (15.0 - 15.0)	4.0 (2.0 - 6.0)	9.0 (6.0 - 14.0)	
Min ; Max	15 ; 15	1 ; 23	1 ; 18	
Red blood cells overall* (count)				
N	0.3	7.8	9.4	0
Mean (SD)	16.0 (NE)	7.4 (3.9)	13.5 (4.5)	
Median (IQR)	16.0 (16.0 - 16.0)	6.0 (3.0 - 12.0)	12.0 (10.0 - 14.0)	
Min ; Max	16 ; 16	1 ; 29	6 ; 24	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Red blood cells from delivery to time0 (mL)				
N	0.3	5.1	8.9	0
Mean (SD)	550.0 (NE)	1113.5 (412.4)	1285.0 (539.2)	
Median (IQR)	550.0 (550.0 - 550.0)	1100.0 (550.0 - 1650.0)	1100.0 (825.0 - 1650.0)	
Min ; Max	550 ; 550	275 ; 2200	550 ; 2750	
Red blood cells from time0 until 24 hours after time0 (mL)				
N	0.3	6.5	9.7	0
Mean (SD)	4125.0 (NE)	1583.0 (863.4)	2598.3 (987.4)	
Median (IQR)	4125.0 (4125.0 - 4125.0)	1100.0 (550.0 - 1650.0)	2475.0 (1650.0 - 3850.0)	
Min ; Max	4125 ; 4125	275 ; 6325	275 ; 4950	
Red blood cells overall* (mL)				
N	0.3	7.8	9.4	0
Mean (SD)	4400.0 (NE)	2047.9 (1063.0)	3723.5 (1231.7)	
Median (IQR)	4400.0 (4400.0 - 4400.0)	1650.0 (825.0 - 3300.0)	3300.0 (2750.0 - 3850.0)	
Min ; Max	4400 ; 4400	275 ; 7975	1650 ; 6600	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
FFP transfusion from delivery to time0 (count)				
N	0.3	4.3	9.2	0
Mean (SD)	1.0 (NE)	4.2 (1.7)	4.0 (1.9)	
Median (IQR)	1.0 (1.0 - 1.0)	4.0 (2.0 - 6.0)	4.0 (3.0 - 4.0)	
Min ; Max	1 ; 1	1 ; 8	1 ; 10	
FFP transfusion from time0 until 24 hours after time0 (count)				
N	0.3	4.8	9.2	0
Mean (SD)	11.0 (NE)	6.6 (3.9)	7.4 (2.3)	
Median (IQR)	11.0 (11.0 - 11.0)	5.0 (2.0 - 8.0)	7.0 (5.0 - 9.0)	
Min ; Max	11 ; 11	1 ; 26	2 ; 13	
FFP transfusion overall* (count)				
N	0.3	6.8	9.7	0
Mean (SD)	12.0 (NE)	7.9 (4.5)	10.6 (4.0)	
Median (IQR)	12.0 (12.0 - 12.0)	5.0 (4.0 - 12.0)	10.0 (8.0 - 12.0)	
Min ; Max	12 ; 12	2 ; 32	4 ; 23	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
FFP transfusion from delivery to time0 (mL)				
N	0.3	4.3	9.2	0
Mean (SD)	280.0 (NE)	1185.9 (479.0)	1130.2 (527.6)	
Median (IQR)	280.0 (280.0 - 280.0)	1120.0 (560.0 - 1680.0)	1120.0 (840.0 - 1120.0)	
Min ; Max	280 ; 280	280 ; 2240	280 ; 2800	
FFP transfusion from time0 until 24 hours after time0 (mL)				
N	0.3	4.8	9.2	0
Mean (SD)	3080.0 (NE)	1834.5 (1097.9)	2082.2 (639.0)	
Median (IQR)	3080.0 (3080.0 - 3080.0)	1400.0 (560.0 - 2240.0)	1960.0 (1400.0 - 2520.0)	
Min ; Max	3080 ; 3080	280 ; 7280	560 ; 3640	
FFP transfusion overall* (mL)				
N	0.3	6.8	9.7	0
Mean (SD)	3360.0 (NE)	2205.4 (1250.2)	2959.3 (1108.4)	
Median (IQR)	3360.0 (3360.0 - 3360.0)	1400.0 (1120.0 - 3360.0)	2800.0 (2240.0 - 3360.0)	
Min ; Max	3360 ; 3360	560 ; 8960	1120 ; 6440	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Platelets from delivery to time0 (count)				
N	0	1.0	2.5	0
Mean (SD)		1.0 (NE)	1.0 (0.0)	
Median (IQR)		1.0 (1.0 - 1.0)	1.0 (1.0 - 1.0)	
Min ; Max		1 ; 1	1 ; 1	
Platelets from time0 until 24 hours after time0 (count)				
N	0.3	2.0	7.4	0
Mean (SD)	3.0 (NE)	1.8 (0.5)	2.0 (0.7)	
Median (IQR)	3.0 (3.0 - 3.0)	1.5 (1.0 - 2.5)	2.0 (1.0 - 3.0)	
Min ; Max	3 ; 3	1 ; 3	1 ; 3	
Platelets overall* (count)				
N	0.3	3.0	7.1	0
Mean (SD)	3.0 (NE)	1.5 (0.5)	2.3 (0.8)	
Median (IQR)	3.0 (3.0 - 3.0)	1.0 (1.0 - 2.0)	2.0 (1.0 - 3.0)	
Min ; Max	3 ; 3	1 ; 3	1 ; 4	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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Concomitant medication - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Platelets from delivery to time0 (mL)				
N	0	1.0	2.5	0
Mean (SD)		125.0 (NE)	125.0 (0.0)	
Median (IQR)		125.0 (125.0 - 125.0)	125.0 (125.0 - 125.0)	
Min ; Max		125 ; 125	125 ; 125	
Platelets from time0 until 24 hours after time0 (mL)				
N	0.3	2.0	7.4	0
Mean (SD)	375.0 (NE)	218.8 (59.8)	251.4 (83.6)	
Median (IQR)	375.0 (375.0 - 375.0)	187.5 (125.0 - 312.5)	250.0 (125.0 - 375.0)	
Min ; Max	375 ; 375	125 ; 375	125 ; 375	
Platelets overall* (mL)				
N	0.3	3.0	7.1	0
Mean (SD)	375.0 (NE)	187.5 (62.5)	283.8 (101.3)	
Median (IQR)	375.0 (375.0 - 375.0)	125.0 (125.0 - 250.0)	250.0 (125.0 - 375.0)	
Min ; Max	375 ; 375	125 ; 375	125 ; 500	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range(25th percentile - 75th percentile), FFP: fresh frozen plasma, NE: Not Estimable.

*Overall is measured in the period from delivery to stop of PPH. Concomitant medications are summarised in the period indicated.

Oxytocin and other uterotonics are summarised based on the number of doses.

Prostaglandin, Ergometrin/Methergine, Misoprostol and Carbetocin/Pabal are considered as other uterotonic doses.

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14.1.23 Clinical outcomes before conjoint period - full analysis set

		PS matched analysis set		Full analysis set	
		NovoSeven®	Controls	NovoSeven®	No NovoSeven® Total
1.0	Number of patients	18	43	52	113
	Number of weighted patients, N		18.0		
	Hysterectomy*, N (%)				
	Yes	0	0	3 (5.8)	
	No	18 (100.0)	18.0 (100.0)	49 (94.2)	
	Missing	0	0	0	
	Other invasive procedure(s)*, N (%)				
	Yes	11 (61.1)	7.0 (38.9)	28 (53.8)	
	No	7 (38.9)	11.0 (61.1)	24 (46.2)	
	Missing	0	0	0	
	Hysterectomy and other invasive procedure(s)*, N (%)				
	Yes	0	0	1 (1.9)	
	No	18 (100.0)	18.0 (100.0)	51 (98.1)	
	Missing	0	0	0	
	Any invasive procedure(s), N (%)				
	Yes	11 (61.1)	7.0 (38.9)	32 (61.5)	
	No	7 (38.9)	11.0 (61.1)	20 (38.5)	
	Missing	0	0	0	
	Laparotomy, N (%)				
	Yes	3 (16.7)	3.3 (18.1)	9 (17.3)	
	No	15 (83.3)	14.8 (81.9)	43 (82.7)	
	Missing	0	0	0	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes before conjoint period - full analysis set

	PS matched analysis set		Full analysis set		
	NovoSeven®	Controls	NovoSeven®	No NovoSeven®	Total
Intrauterine balloon, N (%)					
Yes	0	2.5 (13.9)	6 (11.5)		
No	18 (100.0)	15.5 (86.1)	46 (88.5)		
Missing	0	0	0		
Other tamponade, N (%)					
Yes	2 (11.1)	2.3 (13.0)	10 (19.2)		
No	16 (88.9)	15.7 (87.0)	42 (80.8)		
Missing	0	0	0		
Removal of placenta, N (%)					
Yes	0	0.5 (2.8)	1 (1.9)		
No	18 (100.0)	17.5 (97.2)	51 (98.1)		
Missing	0	0	0		

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.1.24 Clinical outcomes before conjoint period - by concomitant use for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	7	7	1	3
Hysterectomy*, N (%)				
Yes	0	0	0	0
No	7 (100.0)	7 (100.0)	1 (100.0)	3 (100.0)
Missing	0	0	0	0
Other invasive procedure(s)*, N (%)				
Yes	3 (42.9)	5 (71.4)	1 (100.0)	2 (66.7)
No	4 (57.1)	2 (28.6)	0	1 (33.3)
Missing	0	0	0	0
Hysterectomy and other invasive procedure(s)*, N (%)				
Yes	0	0	0	0
No	7 (100.0)	7 (100.0)	1 (100.0)	3 (100.0)
Missing	0	0	0	0
Any invasive procedure(s), N (%)				
Yes	3 (42.9)	5 (71.4)	1 (100.0)	2 (66.7)
No	4 (57.1)	2 (28.6)	0	1 (33.3)
Missing	0	0	0	0
Laparotomy, N (%)				
Yes	1 (14.3)	1 (14.3)	1 (100.0)	0
No	6 (85.7)	6 (85.7)	0	3 (100.0)
Missing	0	0	0	0

PS: Propensity score, TXA: Tranexamic acid, N: Number of patients, %: Percentage of patients.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(=)/after(>) time0. Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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NovoSeven®
Trial ID: NN7711-4729

Non-interventional report
Report body

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Clinical outcomes before conjoint period - by concomitant use for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Intrauterine balloon, N (%)				
Yes	0	0	0	0
No	7 (100.0)	7 (100.0)	1 (100.0)	3 (100.0)
Missing	0	0	0	0
Other tamponade, N (%)				
Yes	1 (14.3)	0	1 (100.0)	0
No	6 (85.7)	7 (100.0)	0	3 (100.0)
Missing	0	0	0	0
Removal of placenta, N (%)				
Yes	0	0	0	0
No	7 (100.0)	7 (100.0)	1 (100.0)	3 (100.0)
Missing	0	0	0	0

PS: Propensity score, TXA: Tranexamic acid, N: Number of patients, %: Percentage of patients.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(=)/after(>) time0. Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.1.25 Clinical outcomes before conjoint period - by concomitant use for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	16	18	1	8
Number of weighted patients, N	5.2	8.8	1.0	3.1
Hysterectomy*, N (%)				
Yes	0	0	0	0
No	5.2 (100.0)	8.8 (100.0)	1.0 (100.0)	3.1 (100.0)
Missing	0	0	0	0
Other invasive procedure(s)*, N (%)				
Yes	0.8 (14.5)	4.8 (54.3)	0	1.5 (48.6)
No	4.4 (85.5)	4.0 (45.7)	1.0 (100.0)	1.6 (51.4)
Missing	0	0	0	0
Hysterectomy and other invasive procedure(s)*, N (%)				
Yes	0	0	0	0
No	5.2 (100.0)	8.8 (100.0)	1.0 (100.0)	3.1 (100.0)
Missing	0	0	0	0
Any invasive procedure(s), N (%)				
Yes	0.8 (14.5)	4.8 (54.3)	0	1.5 (48.6)
No	4.4 (85.5)	4.0 (45.7)	1.0 (100.0)	1.6 (51.4)
Missing	0	0	0	0
Laparotomy, N (%)				
Yes	0.3 (4.8)	2.0 (22.9)	0	1.0 (32.4)
No	4.9 (95.2)	6.8 (77.1)	1.0 (100.0)	2.1 (67.6)
Missing	0	0	0	0

PS: Propensity score, TXA: Tranexamic acid, N: Number of (weighted) patients, %: Percentage of patients.
Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=)/after(>) time0. Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

Clinical outcomes before conjoint period - by concomitant use for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Intrauterine balloon, N (%)				
Yes	1.9 (37.1)	0.3 (2.9)	0	0.3 (10.8)
No	3.3 (62.9)	8.5 (97.1)	1.0 (100.0)	2.8 (89.2)
Missing	0	0	0	0
Other tamponade, N (%)				
Yes	1.3 (25.8)	1.0 (11.4)	0	0
No	3.8 (74.2)	7.8 (88.6)	1.0 (100.0)	3.1 (100.0)
Missing	0	0	0	0
Removal of placenta, N (%)				
Yes	0.5 (9.7)	0	0	0
No	4.7 (90.3)	8.8 (100.0)	1.0 (100.0)	3.1 (100.0)
Missing	0	0	0	0

PS: Propensity score, TXA: Tranexamic acid, N: Number of (weighted) patients, %: Percentage of patients.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(=)/after(>) time0. Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.1.26 Clinical outcomes before conjoint period - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony	Trauma	Other
Number of patients	4	1	0	13	0	0
Hysterectomy*, N (%)						
Yes	0	0	0	0	0	0
No	4 (100.0)	1 (100.0)	0	13 (100.0)	0	0
Missing	0	0	0	0	0	0
Other invasive procedure(s)*, N (%)						
Yes	2 (50.0)	0	0	9 (69.2)	0	0
No	2 (50.0)	1 (100.0)	0	4 (30.8)	0	0
Missing	0	0	0	0	0	0
Hysterectomy and other invasive procedure(s)*, N (%)						
Yes	0	0	0	0	0	0
No	4 (100.0)	1 (100.0)	0	13 (100.0)	0	0
Missing	0	0	0	0	0	0
Any invasive procedure(s), N (%)						
Yes	2 (50.0)	0	0	9 (69.2)	0	0
No	2 (50.0)	1 (100.0)	0	4 (30.8)	0	0
Missing	0	0	0	0	0	0
Laparotomy, N (%)						
Yes	1 (25.0)	0	0	2 (15.4)	0	0
No	3 (75.0)	1 (100.0)	0	11 (84.6)	0	0
Missing	0	0	0	0	0	0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes before conjoint period - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony	Trauma	Other
Intrauterine balloon, N (%)						
Yes	0	0	0	0	0	0
No	4 (100.0)	1 (100.0)	0	13 (100.0)	0	0
Missing	0	0	0	0	0	0
Other tamponade, N (%)						
Yes	1 (25.0)	0	0	1 (7.7)	0	0
No	3 (75.0)	1 (100.0)	0	12 (92.3)	0	0
Missing	0	0	0	0	0	0
Removal of placenta, N (%)						
Yes	0	0	0	0	0	0
No	4 (100.0)	1 (100.0)	0	13 (100.0)	0	0
Missing	0	0	0	0	0	0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.1.27 Clinical outcomes before conjoint period - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony	Trauma	Other
Number of patients	14	3	0	23	2	1
Number of weighted patients, N	5.0	2.3	0	8.4	1.3	1.0
Hysterectomy*, N (%)						
Yes	0	0	0	0	0	0
No	5.0 (100.0)	2.3 (100.0)	0	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0
Other invasive procedure(s)*, N (%)						
Yes	1.7 (33.3)	1.3 (55.6)	0	2.8 (32.7)	0.3 (25.0)	1.0 (100.0)
No	3.3 (66.7)	1.0 (44.4)	0	5.7 (67.3)	1.0 (75.0)	0
Missing	0	0	0	0	0	0
Hysterectomy and other invasive procedure(s)*, N (%)						
Yes	0	0	0	0	0	0
No	5.0 (100.0)	2.3 (100.0)	0	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0
Any invasive procedure(s), N (%)						
Yes	1.7 (33.3)	1.3 (55.6)	0	2.8 (32.7)	0.3 (25.0)	1.0 (100.0)
No	3.3 (66.7)	1.0 (44.4)	0	5.7 (67.3)	1.0 (75.0)	0
Missing	0	0	0	0	0	0
Laparotomy, N (%)						
Yes	0	1.0 (44.4)	0	1.3 (14.9)	0	1.0 (100.0)
No	5.0 (100.0)	1.3 (55.6)	0	7.2 (85.1)	1.3 (100.0)	0
Missing	0	0	0	0	0	0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

Clinical outcomes before conjoint period - by cause of PPH for matched controls - PS analysis set

	AIP		Placental abruption	Placental retention	Uterine Atony		Trauma		Other
Intrauterine balloon, N (%)									
Yes	1.1	(21.7)	0	0	1.4	(16.8)	0		0
No	3.9	(78.3)	2.3	(100.0)	7.0	(83.2)	1.3	(100.0)	1.0 (100.0)
Missing	0		0	0	0		0		0
Other tamponade, N (%)									
Yes	0.5	(10.0)	0	0	0.8	(9.9)	1.0	(75.0)	0
No	4.5	(90.0)	2.3	(100.0)	7.6	(90.1)	0.3	(25.0)	1.0 (100.0)
Missing	0		0	0	0		0		0
Removal of placenta, N (%)									
Yes	0.5	(10.0)	0	0	0		0		0
No	4.5	(90.0)	2.3	(100.0)	8.4	(100.0)	1.3	(100.0)	1.0 (100.0)
Missing	0		0	0	0		0		0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.1.28 Clinical outcomes before conjoint period - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure	After first invasive procedure	Missing
1.0 Number of patients	2	0	15	1	0
Hysterectomy*, N (%)					
Yes	0	0	0	0	0
No	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Missing	0	0	0	0	0
Other invasive procedure(s)*, N (%)					
Yes	0	0	10 (66.7)	1 (100.0)	0
No	2 (100.0)	0	5 (33.3)	0	0
Missing	0	0	0	0	0
Hysterectomy and other invasive procedure(s)*, N (%)					
Yes	0	0	0	0	0
No	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Missing	0	0	0	0	0
Any invasive procedure(s), N (%)					
Yes	0	0	10 (66.7)	1 (100.0)	0
No	2 (100.0)	0	5 (33.3)	0	0
Missing	0	0	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

Clinical outcomes before conjoint period - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure	After first invasive procedure	Missing
1.0 Laparotomy, N (%)					
Yes	0	0	3 (20.0)	0	0
No	2 (100.0)	0	12 (80.0)	1 (100.0)	0
Missing	0	0	0	0	0
Intrauterine balloon, N (%)					
Yes	0	0	0	0	0
No	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Missing	0	0	0	0	0
Other tamponade, N (%)					
Yes	1 (50.0)	0	1 (6.7)	0	0
No	1 (50.0)	0	14 (93.3)	1 (100.0)	0
Missing	0	0	0	0	0
Removal of placenta, N (%)					
Yes	0	0	0	0	0
No	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Missing	0	0	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.1.29 Clinical outcomes before conjoint period - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
1.0 Number of patients	4	14
Hysterectomy*, N (%)		
Yes	0	0
No	4 (100.0)	14 (100.0)
Missing	0	0
Other invasive procedure(s)*, N (%)		
Yes	1 (25.0)	10 (71.4)
No	3 (75.0)	4 (28.6)
Missing	0	0
Hysterectomy and other invasive procedure(s)*, N (%)		
Yes	0	0
No	4 (100.0)	14 (100.0)
Missing	0	0
Any invasive procedure(s), N (%)		
Yes	1 (25.0)	10 (71.4)
No	3 (75.0)	4 (28.6)
Missing	0	0
Laparotomy, N (%)		
Yes	0	3 (21.4)
No	4 (100.0)	11 (78.6)
Missing	0	0

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes before conjoint period - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Intrauterine balloon, N (%)		
Yes	0	0
No	4 (100.0)	14 (100.0)
Missing	0	0
Other tamponade, N (%)		
Yes	0	2 (14.3)
No	4 (100.0)	12 (85.7)
Missing	0	0
Removal of placenta, N (%)		
Yes	0	0
No	4 (100.0)	14 (100.0)
Missing	0	0

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients.
 Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive.
 Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.1.30 Clinical outcomes before conjoint period - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Number of patients	2	16	0
Hysterectomy*, N (%)			
Yes	0	0	0
No	2 (100.0)	16 (100.0)	0
Missing	0	0	0
Other invasive procedure(s)*, N (%)			
Yes	1 (50.0)	10 (62.5)	0
No	1 (50.0)	6 (37.5)	0
Missing	0	0	0
Hysterectomy and other invasive procedure(s)*, N (%)			
Yes	0	0	0
No	2 (100.0)	16 (100.0)	0
Missing	0	0	0
Any invasive procedure(s), N (%)			
Yes	1 (50.0)	10 (62.5)	0
No	1 (50.0)	6 (37.5)	0
Missing	0	0	0
Laparotomy, N (%)			
Yes	0	3 (18.8)	0
No	2 (100.0)	13 (81.3)	0
Missing	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes before conjoint period - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Intrauterine balloon, N (%)			
Yes	0	0	0
No	2 (100.0)	16 (100.0)	0
Missing	0	0	0
Other tamponade, N (%)			
Yes	0	2 (12.5)	0
No	2 (100.0)	14 (87.5)	0
Missing	0	0	0
Removal of placenta, N (%)			
Yes	0	0	0
No	2 (100.0)	16 (100.0)	0
Missing	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.1.31 Clinical outcomes before conjoint period - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	2	11	5	0
Hysterectomy*, N (%)				
Yes	0	0	0	0
No	2 (100.0)	11 (100.0)	5 (100.0)	0
Missing	0	0	0	0
Other invasive procedure(s)*, N (%)				
Yes	0	7 (63.6)	4 (80.0)	0
No	2 (100.0)	4 (36.4)	1 (20.0)	0
Missing	0	0	0	0
Hysterectomy and other invasive procedure(s)*, N (%)				
Yes	0	0	0	0
No	2 (100.0)	11 (100.0)	5 (100.0)	0
Missing	0	0	0	0
Any invasive procedure(s), N (%)				
Yes	0	7 (63.6)	4 (80.0)	0
No	2 (100.0)	4 (36.4)	1 (20.0)	0
Missing	0	0	0	0
Laparotomy, N (%)				
Yes	0	1 (9.1)	2 (40.0)	0
No	2 (100.0)	10 (90.9)	3 (60.0)	0
Missing	0	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes before conjoint period - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Intrauterine balloon, N (%)				
Yes	0	0	0	0
No	2 (100.0)	11 (100.0)	5 (100.0)	0
Missing	0	0	0	0
Other tamponade, N (%)				
Yes	0	0	2 (40.0)	0
No	2 (100.0)	11 (100.0)	3 (60.0)	0
Missing	0	0	0	0
Removal of placenta, N (%)				
Yes	0	0	0	0
No	2 (100.0)	11 (100.0)	5 (100.0)	0
Missing	0	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.1.32 Clinical outcomes before conjoint period - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	1	26	16	0
Number of weighted patients, N	0.3	8.1	9.7	0
Hysterectomy*, N (%)				
Yes	0	0	0	0
No	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
Missing	0	0	0	0
Other invasive procedure(s)*, N (%)				
Yes	0	3.5 (43.3)	3.5 (36.2)	0
No	0.3 (100.0)	4.6 (56.7)	6.2 (63.8)	0
Missing	0	0	0	0
Hysterectomy and other invasive procedure(s)*, N (%)				
Yes	0	0	0	0
No	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
Missing	0	0	0	0
Any invasive procedure(s), N (%)				
Yes	0	3.5 (43.3)	3.5 (36.2)	0
No	0.3 (100.0)	4.6 (56.7)	6.2 (63.8)	0
Missing	0	0	0	0
Laparotomy, N (%)				
Yes	0	0	3.3 (33.6)	0
No	0.3 (100.0)	8.1 (100.0)	6.4 (66.4)	0
Missing	0	0	0	0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes before conjoint period - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Intrauterine balloon, N (%)				
Yes	0	0.8 (10.3)	1.7 (17.2)	0
No	0.3 (100.0)	7.3 (89.7)	8.0 (82.8)	0
Missing	0	0	0	0
Other tamponade, N (%)				
Yes	0	0	2.3 (24.1)	0
No	0.3 (100.0)	8.1 (100.0)	7.3 (75.9)	0
Missing	0	0	0	0
Removal of placenta, N (%)				
Yes	0	0	0.5 (5.2)	0
No	0.3 (100.0)	8.1 (100.0)	9.2 (94.8)	0
Missing	0	0	0	0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. Before conjoint period is defined as the period from start of severe postpartum haemorrhage to 20 min before time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.2 Efficacy data

14.2.1 Patient disposition - full analysis set

	PS analysis set		Full analysis set		
	NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total
Number of patients, N			52	113	165
Number of patients collected from Bern Hospital database, N (%)			52 (100.0)	113 (100.0)	165 (100.0)
Full analysis set with documented sPPH, N (%)			52 (100.0)	113 (100.0)	165 (100.0)
Number of patients with preplanned hysterectomy, N (%)			0	3 (2.7)	3 (1.8)
Number of patients with hysterectomy before sPPH, N (%)			0	0	0
Number of patients not eligible for matching due to insufficient data, N (%)			0	9 (8.0)	9 (5.5)
Number of patients eligible for matching, N (%)			52 (100.0)	101 (89.4)	153 (92.7)
Number of patients with hysterectomy before NovoSeven®, N (%)			5 (9.6)		
Number of patients with PPH stop before NovoSeven® administration, N (%)			7 (13.5)		
Number of patients eligible for matching as exposed, N (%)			40 (76.9)		
Number of patients that were included in matching process as exposed, N (%)			41 (78.8)		

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients, DBL: Database lock. Categories derived based on imputed dates. 'Before' means 20 minutes before time0 and 'after' means 20 minutes to 24hours after time0.

For one patient hysterectomy was masked before the PS matching, hence the patient was included in the matching process as exposed. Then patient was not matched.

For one patient data updates regarding time of hysterectomy changed the patient from not eligible for matching as exposed to eligible. This change was made after the PS DBL.

For another patient hysterectomy was masked before the PS matching, hence the patient was included in the matching process as exposed. Then patient was matched as control after the hysterectomy. The patient was then removed from the PS analysis set.

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Patient disposition - full analysis set

	PS analysis set		Full analysis set			
	NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total	
Number of patients eligible for matching as controls, N (%)			51 (98.1)	101 (89.4)	152 (92.1)	
Number of patients included in the PS analysis set, N (%)	18 (100.0)	43				
Number of weighted patients, N (%)		18.0 (100.0)				
Number of patients stopped having PPH within 24 hours from onset of sPPH, N (%)	17 (94.4)	15.8 (87.5)	48 (92.3)	99 (87.6)	147 (89.1)	
Number of patients that died within 24 hours of time0 without an invasive procedure from time0 to 24 hours after time0 , N (%)	0	0	0			
Number of patients that died within 24 hours of time0 with an invasive procedure, N (%)	0	0	0			
Number of patients discharged from the hospital within 24 hours of time0, without an invasive procedure, N (%)	0	0	0			
Number of patients discharged from the hospital within 24 hours of time0 with an invasive procedure, N (%)	0	0	0			
Number of patients in hospital 24 hours after time0, N (%)	17 (94.4)	16.5 (91.7)	51 (98.1)			

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients, DBL: Database lock. Categories derived based on imputed dates. 'Before' means 20 minutes before time0 and 'after' means 20 minutes to 24hours after time0.

For one patient hysterectomy was masked before the PS matching, hence the patient was included in the matching process as exposed. Then patient was not matched.

For one patient data updates regarding time of hysterectomy changed the patient from not eligible for matching as exposed to eligible. This change was made after the PS DBL.

For another patient hysterectomy was masked before the PS matching, hence the patient was included in the matching process as exposed. Then patient was matched as control after the hysterectomy. The patient was then removed from the PS analysis set.

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Patient disposition - full analysis set

	PS analysis set		Full analysis set		
	NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total

Number of controls exposed to NovoSeven® after the time0, N (%)	10.8	(59.7)

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients, DBL: Database lock. Categories derived based on imputed dates. 'Before' means 20 minutes before time0 and 'after' means 20 minutes to 24hours after time0.
 For one patient hysterectomy was masked before the PS matching, hence the patient was included in the matching process as exposed. Then patient was not matched.
 For one patient data updates regarding time of hysterectomy changed the patient from not eligible for matching as exposed to eligible. This change was made after the PS DBL.
 For another patient hysterectomy was masked before the PS matching, hence the patient was included in the matching process as exposed. Then patient was matched as control after the hysterectomy. The patient was then removed from the PS analysis set.

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14.2.2 Overall summary of patients with invasive procedures - full analysis set

	PS analysis set			Full analysis set		
	NovoSeven®	Matched Controls		NovoSeven®	No NovoSeven®	Total
Number of patients, N	18	43		52	113	165
Number of weighted patients, N		18.0				
Patients without Novoseven® and no invasive procedures, N (%)		2.1 (11.6)			81 (71.7)	81 (49.1)
Patients with only Novoseven®, N (%)	2 (11.1)	1.8 (10.2)		12 (23.1)		12 (7.3)
Patients with at least one other invasive procedure(s), N (%)		4.1 (22.7)			21 (18.6)	21 (12.7)
Patients with hysterectomy, N (%)		1.1 (6.0)			11 (9.7)	11 (6.7)
Patients with at least one invasive procedure(s) (including hysterectomy) before NovoSeven® administration, N (%)	9 (50.0)	3.7 (20.4)		21 (40.4)		21 (12.7)
Patients without invasive procedure(s) before and having any invasive procedure after NovoSeven® administration, N (%)	1 (5.6)	2.0 (11.1)		3 (5.8)		3 (1.8)
Patient with at least one other invasive procedure(s) before and having any invasive procedure(s) after NovoSeven® administration, N (%)	2 (11.1)	1.5 (8.3)		7 (13.5)		7 (4.2)
Patients with no invasive procedure(s) before NovoSeven® administration and at least one procedure(s) in conjoint period, N (%)	4 (22.2)	0.3 (1.4)		5 (9.6)		5 (3.0)

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients.

'Before' means 20 minutes before time0, 'Conjoint' means with in +/- 20 minutes of time0 and 'after' means 20 minutes to 24hours after time0. Only first NovoSeven® administration is considered. Other invasive procedures are defined as uterine or iliac artery ligation, radiological arterial embolisation and uterine compression sutures. Categories derived based on imputed dates. Rows are mutually exclusive.

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Overall summary of patients with invasive procedures - full analysis set

	PS analysis set			Full analysis set		
	NovoSeven®	Matched	Controls	NovoSeven®	No NovoSeven®	Total
Patients with no invasive procedure(s) before and at least one other invasive procedure(s) in conjoint period and getting another after NovoSeven® administration, N (%)	0	0.5	(2.8)	0		0
Patients with at least one other invasive procedure(s) before NovoSeven® administration and at least one procedure(s) in conjoint period, N (%)	0	0		3	(5.8)	3 (1.8)
Patients with at least one other invasive procedure(s) before and at least one other invasive procedure(s) in conjoint period and getting another after NovoSeven® administration, N (%)	0	0		1	(1.9)	1 (0.6)
Patients with NovoSeven® and invasive procedures and any procedures have missing timing, N (%)	0	0		0		0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of (weighted) patients.

'Before' means 20 minutes before time0, 'Conjoint' means with in +/- 20 minutes of time0 and 'after' means 20 minutes to 24hours after time0. Only first NovoSeven® administration is considered. Other invasive procedures are defined as uterine or iliac artery ligation, radiological arterial embolisation and uterine compression sutures. Categories derived based on imputed dates. Rows are mutually exclusive.

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14.2.3 NovoSeven® doses - full analysis set

	PS analysis set	Full analysis set
	NovoSeven®	NovoSeven®
1.0 Number of patients	18	52
Total number of NovoSeven® doses per patient, N (%)		
N	18 (100.0)	52 (100.0)
1 dose	17 (94.4)	46 (88.5)
2 doses	1 (5.6)	6 (11.5)
1st dose of NovoSeven® (µg/kg)		
N	18	52
Mean (SD)	67.4 (7.7)	62.7 (16.7)
Median (IQR)	65.0 (62.1 - 73.8)	63.4 (56.4 - 72.7)
Min ; Max	55.4 ; 84.7	12.0 ; 121.2
2nd dose of NovoSeven® (µg/kg)		
N	1	6
Mean (SD)	84.7 (NE)	72.1 (14.4)
Median (IQR)	84.7 (84.7 - 84.7)	73.2 (65.8 - 84.7)
Min ; Max	84.7 ; 84.7	48.0 ; 87.7

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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NovoSeven® doses - full analysis set

	PS analysis set	Full analysis set
	NovoSeven®	NovoSeven®
Total dose of NovoSeven® (µg/kg)		
N	18	52
Mean (SD)	72.1 (25.1)	71.0 (24.1)
Median (IQR)	65.0 (62.1 - 73.8)	64.0 (60.8 - 73.7)
Min ; Max	55.4 ; 169.5	33.9 ; 169.5
Received only one dose (µg/kg)		
N	17	46
Mean (SD)	66.4 (6.6)	65.0 (12.7)
Median (IQR)	64.3 (62.1 - 72.7)	63.5 (60.8 - 72.7)
Min ; Max	55.4 ; 77.4	33.9 ; 121.2
1st dose of NovoSeven® (mg)		
N	18	52
Mean (SD)	4.7 (0.9)	4.3 (1.4)
Median (IQR)	4.8 (4.0 - 5.0)	4.4 (3.6 - 5.0)
Min ; Max	3.6 ; 7.0	1.0 ; 8.0
Total dose of NovoSeven® (mg)		
N	18	52
Mean (SD)	4.9 (1.6)	4.9 (1.7)
Median (IQR)	4.8 (4.0 - 5.0)	4.8 (3.6 - 5.2)
Min ; Max	3.6 ; 10.0	2.0 ; 10.0

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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14.2.4 NovoSeven® doses (µg/kg) - by concomitant use for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	7	7	1	3
Total number of NovoSeven® doses per patient, N (%)				
N	7 (100.0)	7 (100.0)	1 (100.0)	3 (100.0)
1 dose	6 (85.7)	7 (100.0)	1 (100.0)	3 (100.0)
2 doses	1 (14.3)	0	0	0
1st dose of NovoSeven® (µg/kg)				
N	7	7	1	3
Mean (SD)	68.3 (9.2)	68.5 (6.8)	73.8 (NE)	60.7 (4.6)
Median (IQR)	65.8 (60.9 - 72.7)	66.4 (62.1 - 75.0)	73.8 (73.8 - 73.8)	63.2 (55.4 - 63.5)
Min ; Max	57.5 ; 84.7	60.6 ; 77.4	73.8 ; 73.8	55.4 ; 63.5
2nd dose of NovoSeven® (µg/kg)				
N	1	0	0	0
Mean (SD)	84.7 (NE)			
Median (IQR)	84.7 (84.7 - 84.7)			
Min ; Max	84.7 ; 84.7			

PS: Propensity score, TXA: Tranexamic acid, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.
Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(=)/after(>) time0.

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NovoSeven® doses (µg/kg) - by concomitant use for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Total dose of NovoSeven® (µg/kg)				
N	7	7	1	3
Mean (SD)	80.4 (39.7)	68.5 (6.8)	73.8 (NE)	60.7 (4.6)
Median (IQR)	65.8 (60.9 - 72.7)	66.4 (62.1 - 75.0)	73.8 (73.8 - 73.8)	63.2 (55.4 - 63.5)
Min ; Max	57.5 ; 169.5	60.6 ; 77.4	73.8 ; 73.8	55.4 ; 63.5
Received only one dose (µg/kg)				
N	6	7	1	3
Mean (SD)	65.5 (6.2)	68.5 (6.8)	73.8 (NE)	60.7 (4.6)
Median (IQR)	64.6 (60.9 - 72.7)	66.4 (62.1 - 75.0)	73.8 (73.8 - 73.8)	63.2 (55.4 - 63.5)
Min ; Max	57.5 ; 72.7	60.6 ; 77.4	73.8 ; 73.8	55.4 ; 63.5
1st dose of NovoSeven® (mg)				
N	7	7	1	3
Mean (SD)	4.9 (1.1)	4.5 (0.9)	4.8 (NE)	4.6 (0.9)
Median (IQR)	5.0 (4.0 - 5.0)	4.8 (3.6 - 5.0)	4.8 (4.8 - 4.8)	4.8 (3.6 - 5.4)
Min ; Max	4.0 ; 7.0	3.6 ; 6.0	4.8 ; 4.8	3.6 ; 5.4
Total dose of NovoSeven® (mg)				
N	7	7	1	3
Mean (SD)	5.6 (2.2)	4.5 (0.9)	4.8 (NE)	4.6 (0.9)
Median (IQR)	5.0 (4.0 - 7.0)	4.8 (3.6 - 5.0)	4.8 (4.8 - 4.8)	4.8 (3.6 - 5.4)
Min ; Max	4.0 ; 10.0	3.6 ; 6.0	4.8 ; 4.8	3.6 ; 5.4

PS: Propensity score, TXA: Tranexamic acid, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.
Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=)/after(>) time0.

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14.2.5 NovoSeven® doses (µg/kg) - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony
Number of patients	4	1	0	13
Total number of NovoSeven® doses per patient, N (%)				
N	4 (100.0)	1 (100.0)	0	13 (100.0)
1 dose	3 (75.0)	1 (100.0)	0	13 (100.0)
2 doses	1 (25.0)	0	0	0
1st dose of NovoSeven® (µg/kg)				
N	4	1	0	13
Mean (SD)	74.2 (9.5)	57.5 (NE)		66.1 (6.1)
Median (IQR)	75.1 (67.4 - 81.1)	57.5 (57.5 - 57.5)		64.3 (63.2 - 72.7)
Min ; Max	62.1 ; 84.7	57.5 ; 57.5		55.4 ; 75.0
2nd dose of NovoSeven® (µg/kg)				
N	1	0	0	0
Mean (SD)	84.7 (NE)			
Median (IQR)	84.7 (84.7 - 84.7)			
Min ; Max	84.7 ; 84.7			

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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NovoSeven® doses (µg/kg) - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	Trauma	Other
Number of patients	0	0
Total number of NovoSeven® doses per patient, N (%)		
N	0	0
1 dose	0	0
2 doses	0	0
1st dose of NovoSeven® (µg/kg)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
2nd dose of NovoSeven® (µg/kg)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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NovoSeven® doses (µg/kg) - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony
Total dose of NovoSeven® (µg/kg)				
N	4	1	0	13
Mean (SD)	95.4 (49.8)	57.5 (NE)		66.1 (6.1)
Median (IQR)	75.1 (67.4 - 123.5)	57.5 (57.5 - 57.5)		64.3 (63.2 - 72.7)
Min ; Max	62.1 ; 169.5	57.5 ; 57.5		55.4 ; 75.0
Received only one dose (µg/kg)				
N	3	1	0	13
Mean (SD)	70.7 (7.9)	57.5 (NE)		66.1 (6.1)
Median (IQR)	72.7 (62.1 - 77.4)	57.5 (57.5 - 57.5)		64.3 (63.2 - 72.7)
Min ; Max	62.1 ; 77.4	57.5 ; 57.5		55.4 ; 75.0
1st dose of NovoSeven® (mg)				
N	4	1	0	13
Mean (SD)	4.1 (0.7)	5.0 (NE)		4.8 (1.0)
Median (IQR)	3.8 (3.6 - 4.5)	5.0 (5.0 - 5.0)		4.8 (4.0 - 5.0)
Min ; Max	3.6 ; 5.0	5.0 ; 5.0		3.6 ; 7.0
Total dose of NovoSeven® (mg)				
N	4	1	0	13
Mean (SD)	5.3 (3.1)	5.0 (NE)		4.8 (1.0)
Median (IQR)	3.8 (3.6 - 7.0)	5.0 (5.0 - 5.0)		4.8 (4.0 - 5.0)
Min ; Max	3.6 ; 10.0	5.0 ; 5.0		3.6 ; 7.0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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NovoSeven® doses (µg/kg) - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	Trauma	Other
Total dose of NovoSeven® (µg/kg)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Received only one dose (µg/kg)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
1st dose of NovoSeven® (mg)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Total dose of NovoSeven® (mg)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %:
Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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14.2.6 NovoSeven® doses (µg/kg) - by timing of first NovoSeven® dose from invasive procedure - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
Number of patients	2	0	15
Total number of NovoSeven® doses per patient, N (%)			
N	2 (100.0)	0	15 (100.0)
1 dose	2 (100.0)	0	14 (93.3)
2 doses	0	0	1 (6.7)
1st dose of NovoSeven® (µg/kg)			
N	2	0	15
Mean (SD)	73.9 (1.6)		67.4 (7.5)
Median (IQR)	73.9 (72.7 - 75.0)		64.3 (62.1 - 73.8)
Min ; Max	72.7 ; 75.0		57.5 ; 84.7
2nd dose of NovoSeven® (µg/kg)			
N	0	0	1
Mean (SD)			84.7 (NE)
Median (IQR)			84.7 (84.7 - 84.7)
Min ; Max			84.7 ; 84.7

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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NovoSeven® doses (µg/kg) - by timing of first NovoSeven® dose from invasive procedure - PS analysis set

After first invasive procedure Missing

Number of patients	1	0
Total number of NovoSeven® doses per patient, N (%)		
N	1 (100.0)	0
1 dose	1 (100.0)	0
2 doses	0	0
1st dose of NovoSeven® (µg/kg)		
N	1	0
Mean (SD)	55.4 (NE)	
Median (IQR)	55.4 (55.4 - 55.4)	
Min ; Max	55.4 ; 55.4	
2nd dose of NovoSeven® (µg/kg)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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NovoSeven® doses (µg/kg) - by timing of first NovoSeven® dose from invasive procedure - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
Total dose of NovoSeven® (µg/kg)			
N	2	0	15
Mean (SD)	73.9 (1.6)		73.0 (27.3)
Median (IQR)	73.9 (72.7 - 75.0)		64.3 (62.1 - 73.8)
Min ; Max	72.7 ; 75.0		57.5 ; 169.5
Received only one dose (µg/kg)			
N	2	0	14
Mean (SD)	73.9 (1.6)		66.1 (6.0)
Median (IQR)	73.9 (72.7 - 75.0)		63.9 (62.1 - 72.7)
Min ; Max	72.7 ; 75.0		57.5 ; 77.4
1st dose of NovoSeven® (mg)			
N	2	0	15
Mean (SD)	4.4 (0.6)		4.8 (0.9)
Median (IQR)	4.4 (4.0 - 4.8)		4.8 (4.0 - 5.0)
Min ; Max	4.0 ; 4.8		3.6 ; 7.0
Total dose of NovoSeven® (mg)			
N	2	0	15
Mean (SD)	4.4 (0.6)		5.1 (1.6)
Median (IQR)	4.4 (4.0 - 4.8)		4.8 (4.0 - 5.4)
Min ; Max	4.0 ; 4.8		3.6 ; 10.0

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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NovoSeven® doses (µg/kg) - by timing of first NovoSeven® dose from invasive procedure - PS analysis set

	After first invasive procedure	Missing
Total dose of NovoSeven® (µg/kg)		
N	1	0
Mean (SD)	55.4 (NE)	
Median (IQR)	55.4 (55.4 - 55.4)	
Min ; Max	55.4 ; 55.4	
Received only one dose (µg/kg)		
N	1	0
Mean (SD)	55.4 (NE)	
Median (IQR)	55.4 (55.4 - 55.4)	
Min ; Max	55.4 ; 55.4	
1st dose of NovoSeven® (mg)		
N	1	0
Mean (SD)	3.6 (NE)	
Median (IQR)	3.6 (3.6 - 3.6)	
Min ; Max	3.6 ; 3.6	
Total dose of NovoSeven® (mg)		
N	1	0
Mean (SD)	3.6 (NE)	
Median (IQR)	3.6 (3.6 - 3.6)	
Min ; Max	3.6 ; 3.6	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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14.2.7 NovoSeven® doses (µg/kg) - by first NovoSeven® administration time from onset of sPPH - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Number of patients	4	14
Total number of NovoSeven® doses per patient, N (%)		
N	4 (100.0)	14 (100.0)
1 dose	4 (100.0)	13 (92.9)
2 doses	0	1 (7.1)
1st dose of NovoSeven® (µg/kg)		
N	4	14
Mean (SD)	64.1 (6.7)	68.3 (8.0)
Median (IQR)	63.2 (59.0 - 69.3)	65.4 (63.2 - 73.8)
Min ; Max	57.5 ; 72.7	55.4 ; 84.7
2nd dose of NovoSeven® (µg/kg)		
N	0	1
Mean (SD)		84.7 (NE)
Median (IQR)		84.7 (84.7 - 84.7)
Min ; Max		84.7 ; 84.7

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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NovoSeven® doses (µg/kg) - by first NovoSeven® administration time from onset of sPPH - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Total dose of NovoSeven® (µg/kg)		
N	4	14
Mean (SD)	64.1 (6.7)	74.4 (28.1)
Median (IQR)	63.2 (59.0 - 69.3)	65.4 (63.2 - 73.8)
Min ; Max	57.5 ; 72.7	55.4 ; 169.5
Received only one dose (µg/kg)		
N	4	13
Mean (SD)	64.1 (6.7)	67.1 (6.7)
Median (IQR)	63.2 (59.0 - 69.3)	64.3 (63.2 - 73.8)
Min ; Max	57.5 ; 72.7	55.4 ; 77.4
1st dose of NovoSeven® (mg)		
N	4	14
Mean (SD)	4.8 (0.5)	4.6 (1.0)
Median (IQR)	5.0 (4.5 - 5.0)	4.8 (3.6 - 5.0)
Min ; Max	4.0 ; 5.0	3.6 ; 7.0
Total dose of NovoSeven® (mg)		
N	4	14
Mean (SD)	4.8 (0.5)	5.0 (1.8)
Median (IQR)	5.0 (4.5 - 5.0)	4.8 (3.6 - 5.4)
Min ; Max	4.0 ; 5.0	3.6 ; 10.0

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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14.2.8 NovoSeven® doses (µg/kg) - by first dose of NovoSeven® (µg/kg) - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Number of patients	2	16	0
Total number of NovoSeven® doses per patient, N (%)			
N	2 (100.0)	16 (100.0)	0
1 dose	2 (100.0)	15 (93.8)	0
2 doses	0	1 (6.3)	0
1st dose of NovoSeven® (µg/kg)			
N	2	16	0
Mean (SD)	56.4 (1.5)	68.8 (7.1)	
Median (IQR)	56.4 (55.4 - 57.5)	66.1 (63.3 - 73.8)	
Min ; Max	55.4 ; 57.5	60.6 ; 84.7	
2nd dose of NovoSeven® (µg/kg)			
N	0	1	0
Mean (SD)		84.7 (NE)	
Median (IQR)		84.7 (84.7 - 84.7)	
Min ; Max		84.7 ; 84.7	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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NovoSeven® doses (µg/kg) - by first dose of NovoSeven® (µg/kg) - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Total dose of NovoSeven® (µg/kg)			
N	2	16	0
Mean (SD)	56.4 (1.5)	74.1 (26.1)	
Median (IQR)	56.4 (55.4 - 57.5)	66.1 (63.3 - 73.8)	
Min ; Max	55.4 ; 57.5	60.6 ; 169.5	
Received only one dose (µg/kg)			
N	2	15	0
Mean (SD)	56.4 (1.5)	67.7 (5.8)	
Median (IQR)	56.4 (55.4 - 57.5)	65.8 (63.2 - 73.8)	
Min ; Max	55.4 ; 57.5	60.6 ; 77.4	
1st dose of NovoSeven® (mg)			
N	2	16	0
Mean (SD)	4.3 (1.0)	4.7 (0.9)	
Median (IQR)	4.3 (3.6 - 5.0)	4.8 (4.0 - 5.0)	
Min ; Max	3.6 ; 5.0	3.6 ; 7.0	
Total dose of NovoSeven® (mg)			
N	2	16	0
Mean (SD)	4.3 (1.0)	5.0 (1.6)	
Median (IQR)	4.3 (3.6 - 5.0)	4.8 (4.0 - 5.2)	
Min ; Max	3.6 ; 5.0	3.6 ; 10.0	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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14.2.9 NovoSeven® doses (µg/kg) - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	2	11	5	0
Total number of NovoSeven® doses per patient, N (%)				
N	2 (100.0)	11 (100.0)	5 (100.0)	0
1 dose	2 (100.0)	10 (90.9)	5 (100.0)	0
2 doses	0	1 (9.1)	0	0
1st dose of NovoSeven® (µg/kg)				
N	2	11	5	0
Mean (SD)	70.4 (6.5)	66.2 (8.8)	68.9 (6.3)	
Median (IQR)	70.4 (65.8 - 75.0)	63.5 (60.6 - 72.7)	72.7 (63.2 - 73.8)	
Min ; Max	65.8 ; 75.0	55.4 ; 84.7	60.9 ; 73.8	
2nd dose of NovoSeven® (µg/kg)				
N	0	1	0	0
Mean (SD)		84.7 (NE)		
Median (IQR)		84.7 (84.7 - 84.7)		
Min ; Max		84.7 ; 84.7		

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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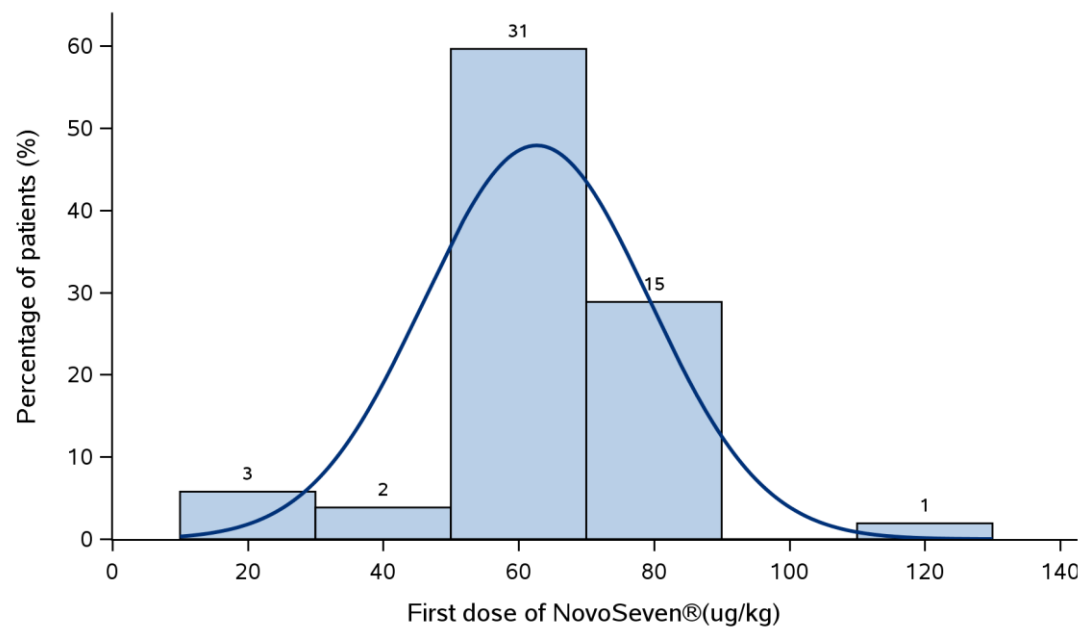
NovoSeven® doses (µg/kg) - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Total dose of NovoSeven® (µg/kg)				
N	2	11	5	0
Mean (SD)	70.4 (6.5)	73.9 (32.3)	68.9 (6.3)	
Median (IQR)	70.4 (65.8 - 75.0)	63.5 (60.6 - 72.7)	72.7 (63.2 - 73.8)	
Min ; Max	65.8 ; 75.0	55.4 ; 169.5	60.9 ; 73.8	
Received only one dose (µg/kg)				
N	2	10	5	0
Mean (SD)	70.4 (6.5)	64.3 (6.6)	68.9 (6.3)	
Median (IQR)	70.4 (65.8 - 75.0)	63.5 (60.6 - 66.4)	72.7 (63.2 - 73.8)	
Min ; Max	65.8 ; 75.0	55.4 ; 77.4	60.9 ; 73.8	
1st dose of NovoSeven® (mg)				
N	2	11	5	0
Mean (SD)	4.9 (0.1)	4.4 (0.9)	5.1 (1.1)	
Median (IQR)	4.9 (4.8 - 5.0)	4.0 (3.6 - 5.0)	4.8 (4.8 - 4.8)	
Min ; Max	4.8 ; 5.0	3.6 ; 6.0	4.0 ; 7.0	
Total dose of NovoSeven® (mg)				
N	2	11	5	0
Mean (SD)	4.9 (0.1)	4.9 (1.9)	5.1 (1.1)	
Median (IQR)	4.9 (4.8 - 5.0)	4.0 (3.6 - 5.4)	4.8 (4.8 - 4.8)	
Min ; Max	4.8 ; 5.0	3.6 ; 10.0	4.0 ; 7.0	

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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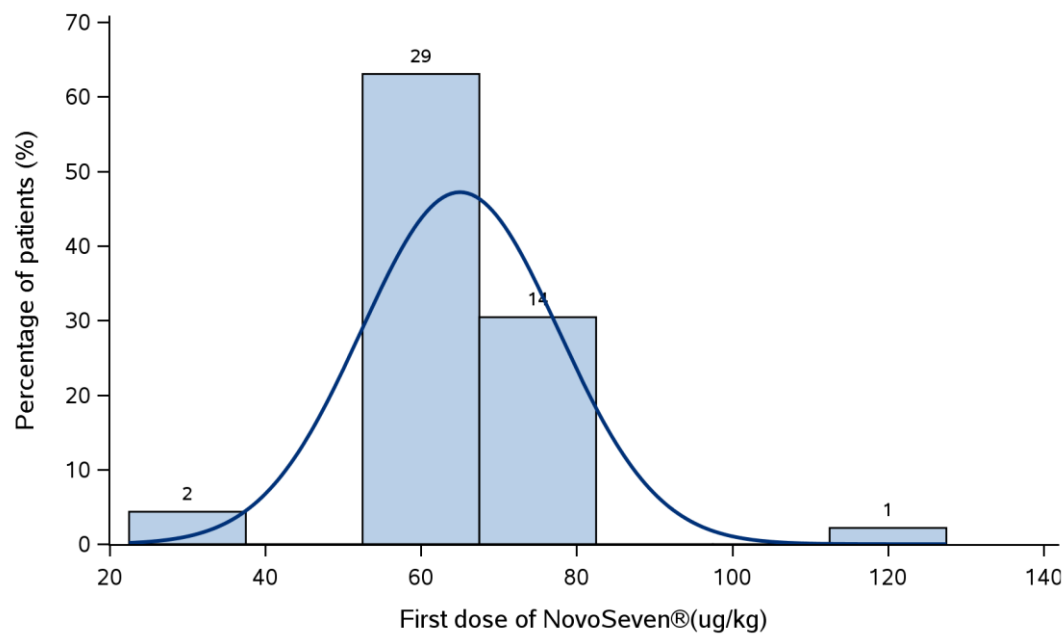
14.2.10 First dose of NovoSeven® (µg/kg) - histogram - full analysis set



N: Number of patients are displayed at the end of each bin.

/fvi/nn7711-4729/ctr_20210821_er
18AUG2021:14:40:47 - fhst.sas/fhstfnsfas.png

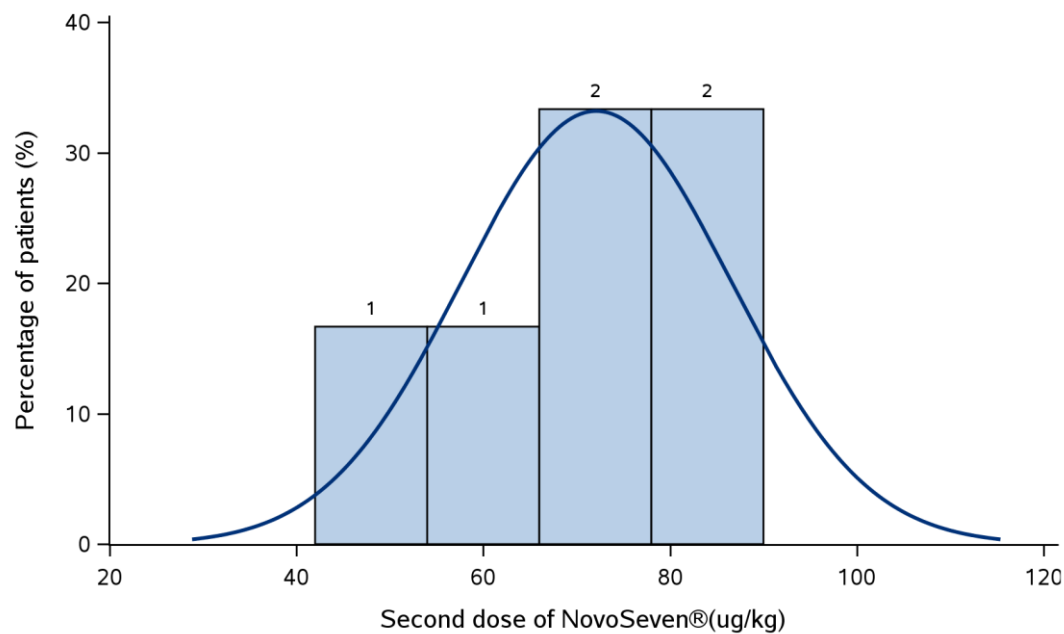
14.2.11 First dose of NovoSeven® (µg/kg) - receiving exactly one dose of NovoSeven® - histogram - full analysis set



N: Number of patients are displayed at the end of each bin.

//vii/nn7711-4729/ctr_20210821_er
18AUG2021:14:40:54 - fhst.sas/fhstfirstnsodfas.png

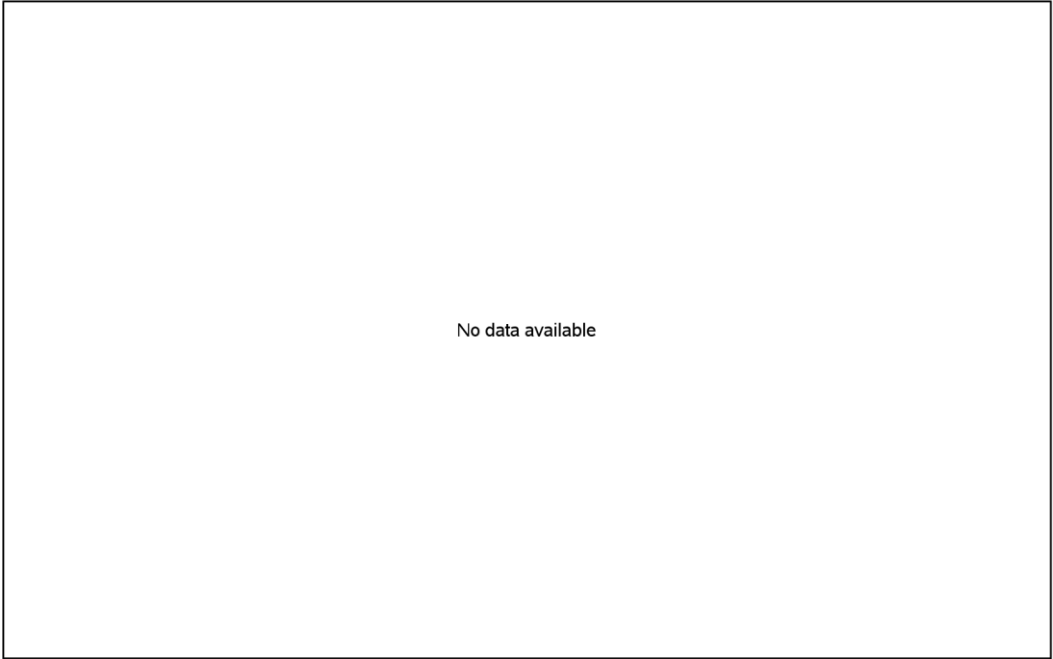
14.2.12 Second dose of NovoSeven® (µg/kg) - receiving more than one dose of NovoSeven® - histogram - full analysis set



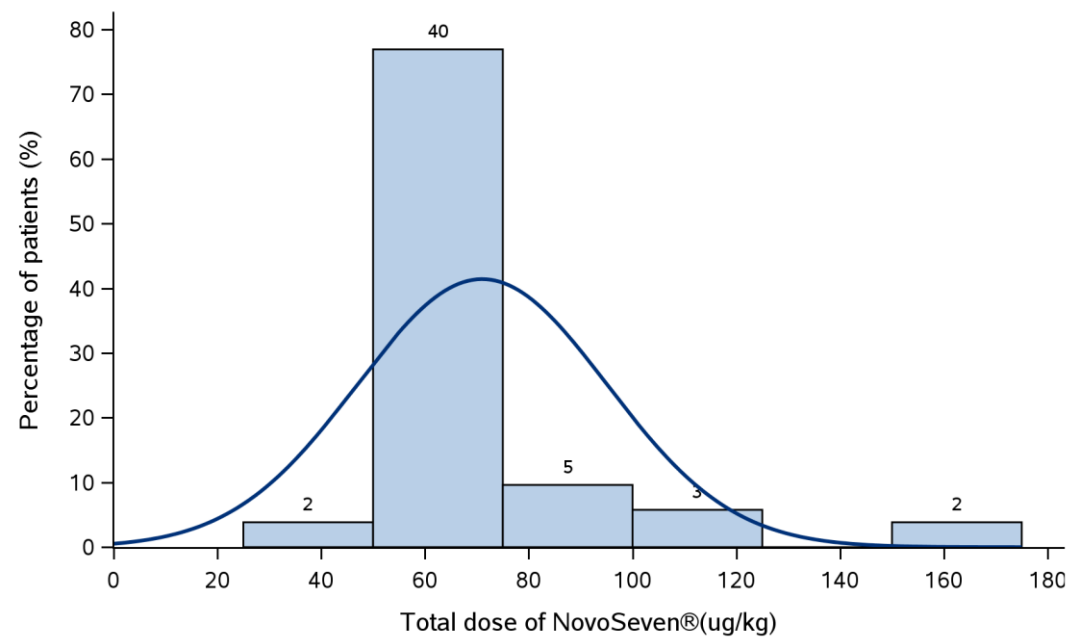
N: Number of patients are displayed at the end of each bin.

//vii/nn7711-4729/ctr_20210821_er
18AUG2021:14:40:52 - fhist.sas/fhistsecondnsmodfas.png

14.2.13 Third dose of NovoSeven® (µg/kg) - receiving more than two doses of NovoSeven® - histogram - full analysis set



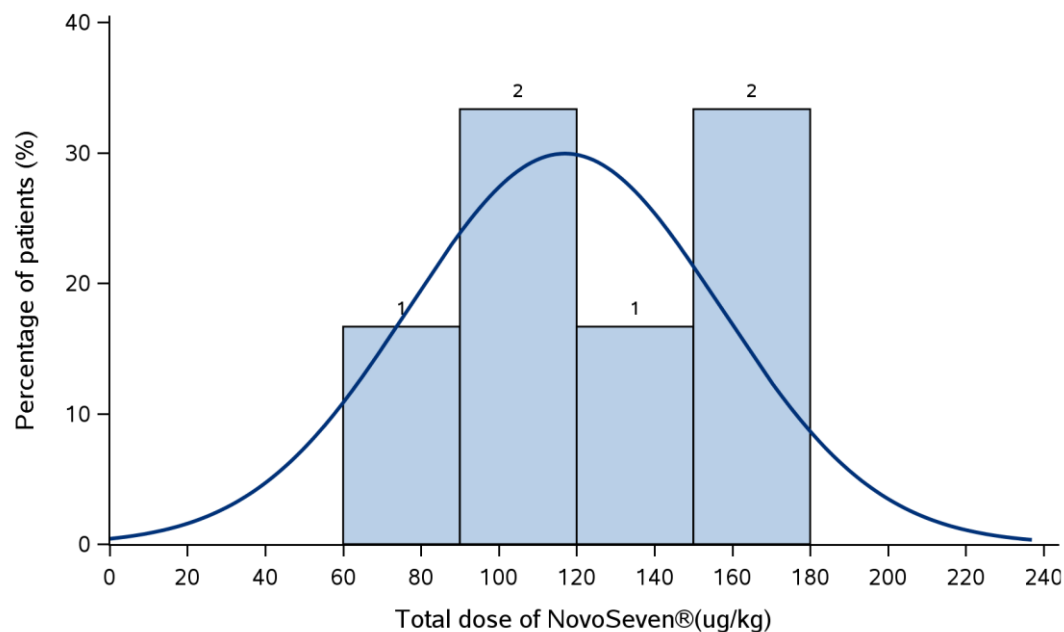
14.2.14 Total dose of NovoSeven® (µg/kg) - histogram - full analysis set



N: Number of patients are displayed at the end of each bin.

//vii/nn7711-4729/ctr_20210821_er
18AUG2021:14:40:55 - fhst.sas/fhsttotalnsfas.png

14.2.15 Total dose of NovoSeven® (µg/kg) - receiving more than one doses of NovoSeven® - histogram - full analysis set



N: Number of patients are displayed at the end of each bin.

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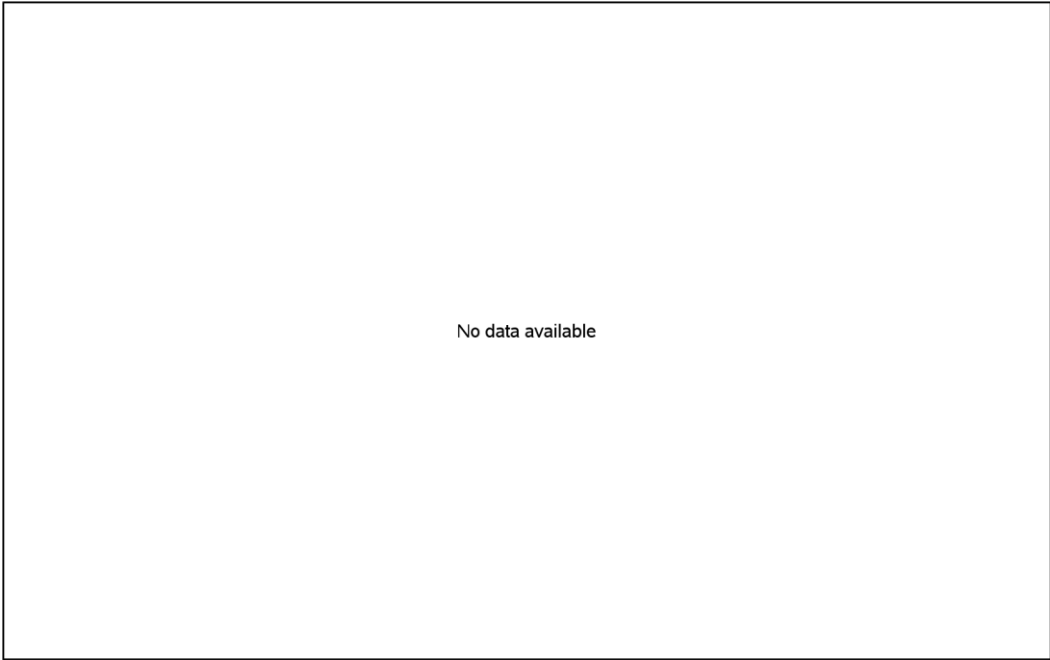
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14.2.16 Total dose of NovoSeven® (µg/kg) - receiving more than two doses of NovoSeven® - histogram - full analysis set



14.2.17 Primary endpoint - invasive procedure - summary- PS analysis set

	NovoSeven®	Matched controls
Number of patients	18	43
Number of patients at risk	18	43
Patients having invasive procedure after time0, N (%)		
N	18 (100.0)	18.0 (100.0)
Yes	3 (16.7)	5.6 (31.0)
No	15 (83.3)	12.4 (69.0)
Missing	0	0
Patients having at least one other invasive procedure before or in conjoint period and receiving another after time0, N (%)		
N	15 (83.3)	9.8 (54.2)
Yes	2 (11.1)	2.3 (12.5)
No	13 (72.2)	7.5 (41.7)
Missing	0	0
Patients without invasive procedure before or in conjoint period and receiving one after time0, N (%)		
N	3 (16.7)	8.3 (45.8)
Yes	1 (5.6)	3.3 (18.5)
No	2 (11.1)	4.9 (27.3)
Invasive procedure after time0, N (%)		
N	18 (100.0)	18.0 (100.0)
Hysterectomy	2 (11.1)	3.1 (17.1)
Radiological arterial embolisation	1 (5.6)	1.0 (5.6)
Uterine compression sutures	1 (5.6)	2.8 (15.3)
Uterine or iliac artery ligation	0	0.8 (4.2)
Other*	0	0
No	15 (83.3)	12.4 (69.0)
Missing	0	0

N: Number of (weighted) patients, %: Percentage of patients.

*Death is imputed as other invasive procedure. Patient at risk: with/without invasive procedures other than hysterectomy before time0.

'Before' means 20 minutes before time0, 'Conjoint' means with in +/- 20 minutes of time0 and 'after' means 20 minutes to 24hours after time0. Invasive procedure with missing time will be counted in Missing category while comparing with time0.

Two controls (■■■, ■■■) had an invasive procedure after 24 hours window are not considered in the primary analysis.

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18AUG2021:14:44:47 - tsumpeip.sas/tsumpeippsas.txt

14.2.18 Primary endpoint - invasive procedure - statistical analysis - PS analysis set

	PSAS	N	n	Estimate	95% CI	p-value
Invasive Procedure						
Observed data						
NovoSeven®	18	18	3	16.7		
Matched controls	43	42	13	31.0		
Weighted data						
NovoSeven®	18	18	3	16.7	[-2.4 ; 35.7]	
Matched controls	18.0	17.8	5.6	31.5	[16.8 ; 46.1]	
Adjusted Odds ratio						
NovoSeven®/Matched controls				0.33	[0.03 ; 1.75]	0.2691

PS: Propensity score, PSAS: Propensity score analysis set, N: Number of (weighted) Patients used in analysis, n: Number of (weighted) patients having invasive procedure, CI: confidence interval.

Observed data is the raw proportion of events in each group. The weighted data is the proportion with 95% Wald's confidence interval in each group where the matched controls are weighted according to number of controls selected in the matching process to adjust for difference in number of controls across NovoSeven® exposed women. Odds ratio for invasive procedures were compared between NovoSeven® and matched control based on an exact conditional logistic regression model with a 95% exact confidence interval based on the propensity score matching, along with p-value. Patient with hysterectomy in the conjoint period are excluded from the PS analysis set (0 patients with NovoSeven® and 1 matched control).

Two controls (■■■■, ■■■■) had an invasive procedure after 24 hours window are not considered in the primary analysis.

14.2.19 Primary endpoint - invasive procedures - by with or without invasive procedures before matching - statistical analysis - PS analysis set

	PSAS	N	n	Estimate	95% CI	p-value
Invasive procedures before matching						
1.0	Invasive Procedure					
	Observed data					
	NovoSeven®	15	11	1	9.1	
	Matched controls	26	21	4	19.0	
	Weighted data					
	NovoSeven®	15	11	1	9.1	[-11.2 ; 29.3]
	Matched controls	9.8	8.5	1.8	20.6	[1.7 ; 39.4]
	Adjusted Odds ratio					
	NovoSeven®/Matched controls			0.41	[0.01 ; 5.48]	0.8125
No invasive procedures before matching						
	Invasive Procedure					
	Observed data					
	NovoSeven®	3	2	1	50.0	
	Matched controls	17	3	2	66.7	
	Weighted data					
	NovoSeven®	3	2	1	50.0	[-585.3 ; 685.3]
	Matched controls	8.3	2.0	1.0	50.0	[-102.1 ; 202.1]
	Adjusted Odds ratio					
	NovoSeven®/Matched controls			0.71	[0.01 ; 58.83]	1.0000

PS: Propensity score, PSAS: Propensity score analysis set, N: Number of (weighted) Patients used in analysis, n: Number of (weighted) patients having invasive procedure, CI: confidence interval.

Observed data is the raw proportion of events in each group. The weighted data is the proportion with 95% Wald's confidence interval in each group where the matched controls are weighted according to number of controls selected in the matching process to adjust for difference in number of controls across NovoSeven® exposed women. Odds ratio for invasive procedures were compared between NovoSeven® and matched control based on an exact conditional logistic regression model with a 95% exact confidence interval based on the propensity score matching, along with p-value. Patient with hysterectomy in the conjoint period are excluded from the PS analysis set (0 patients with NovoSeven® and 1 matched controls).

Two controls (■■■, ■■■) had an invasive procedure after 24 hours window are not considered in the primary analysis.

14.2.20 Primary endpoint - invasive procedures - by vaginal delivery or caesarean section - statistical analysis - PS analysis set

	PSAS	N	n	Estimate	95% CI	p-value
Women with vaginal delivery						
Invasive Procedure						
Observed data						
NovoSeven®	2	2	1	50.0		
Matched controls	3	3	2	66.7		
Weighted data						
NovoSeven®	2	2	1	50.0	[-585.3 ; 685.3]	
Matched controls	2.0	2.0	1.0	50.0	[-102.1 ; 202.1]	
Adjusted Odds ratio						
NovoSeven®/Matched controls				0.71	[0.01 ; 58.83]	1.0000
Women with caesarean section						
Invasive Procedure						
Observed data						
NovoSeven®	16	16	2	12.5		
Matched controls	40	39	11	28.2		
Weighted data						
NovoSeven®	16	16	2	12.5	[-5.7 ; 30.7]	
Matched controls	16.0	15.8	4.6	29.1	[14.2 ; 44.0]	
Adjusted Odds ratio						
NovoSeven®/Matched controls				0.23	[0.00 ; 1.86]	0.2628

PS: Propensity score, PSAS: Propensity score analysis set, N: Number of (weighted) Patients used in analysis, n: Number of (weighted) patients having invasive procedure, CI: confidence interval.
Observed data is the raw proportion of events in each group. The weighted data is the proportion with 95% Wald's confidence interval in each group where the matched controls are weighted according to number of controls selected in the matching process to adjust for difference in number of controls across NovoSeven® exposed women. Odds ratio for invasive procedures were compared between NovoSeven® and matched control based on an exact conditional logistic regression model with a 95% exact confidence interval based on the propensity score matching, along with p-value. Patient with hysterectomy in the conjoint period are excluded from the PS analysis set (0 patients with NovoSeven® and 1 matched control).
Two controls (■■■, ■■■) had an invasive procedure after 24 hours window are not considered in the primary analysis.

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14.2.21 Primary endpoint - invasive procedure - statistical analysis - robustness check - PS analysis set

	PSAS	N	n	Estimate	95% CI	p-value
Invasive Procedure						
Observed data						
NovoSeven®	18	18	3	16.7		
Matched controls	43	42	13	31.0		
Weighted data						
NovoSeven®	18	18	3	16.7	[-2.4 ; 35.7]	
Matched controls	18.0	17.8	5.6	31.5	[16.8 ; 46.1]	
Adjusted Odds ratio						
NovoSeven®/Matched controls				0.40	[0.09 ; 1.77]	0.2199

PS: Propensity score, PSAS: Propensity score analysis set, N: Number of (weighted) Patients used in analysis, n: Number of patients having invasive procedure, CI: confidence interval.

Observed proportion are the raw proportion of events in each group. The Adjusted proportion with 95% Wald's confidence interval in the proportion in each group where the matched controls are weighted according to number of controls selected in the matching process to adjust for difference in number of controls across NovoSeven® exposed women. Odds ratio for invasive procedures were compared between NovoSeven® and matched control using logistic regression model based on propensity score matching, including family cluster as random effect and propensity score as a covariate, with a 95% confidence interval along with p-value. Patient with hysterectomy in the conjoint period are excluded from the PS analysis set (0 patients with NovoSeven® and 1 matched control).

Two controls (,) had an invasive procedure after 24 hours window are not considered in the primary analysis.

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18AUG2021:14:41:46 - tstatpeiprobust.sas/tstatpeiprobustpsas.txt

14.2.22 Primary endpoint - invasive procedure - sensitivity analysis - lag time 10 mins to 24 hours after time0 - PS analysis set

	PSAS	N	n	Estimate	95% CI	p-value
Invasive Procedure						
Observed data						
NovoSeven®	18	18	3	16.7		
Matched controls	43	42	14	33.3		
Weighted data						
NovoSeven®	18	18	3	16.7	[-2.4 ; 35.7]	
Matched controls	18.0	17.8	5.8	32.9	[18.0 ; 47.7]	
Adjusted Odds ratio						
NovoSeven®/Matched controls				0.30	[0.03 ; 1.55]	0.2042

PS: Propensity score, PSAS: Propensity score analysis set, N: Number of (weighted) Patients used in analysis, n: Number of (weighted) patients having invasive procedure, CI: confidence interval.

Observed data is the raw proportion of events in each group. The weighted data is the proportion with 95% Wald's confidence interval in each group where the matched controls are weighted according to number of controls selected in the matching process to adjust for difference in number of controls across NovoSeven® exposed women. Odds ratio for invasive procedures were compared between NovoSeven® and matched control based on an exact conditional logistic regression model with a 95% exact confidence interval based on the propensity score matching, along with p-value.

Patient with hysterectomy in the period from time0 to time0+10 minutes are excluded from the PS analysis set (0 patients with NovoSeven® and 1 matched control).

Two controls (■■■■, ■■■■) had an invasive procedure after 24 hours window are not considered in the primary analysis.

/fvii/nn7711-4729/ctr_20210821_er
18AUG2021:14:41:47 - tstatpeipsenlag10.sas/tstatpeipsenlag10psas.txt

14.2.23 Primary endpoint - invasive procedure - sensitivity analysis - lag time 30 mins to 24 hours after time0 - PS analysis set

	PSAS	N	n	Estimate	95% CI	p-value
Invasive Procedure						
Observed data						
NovoSeven®	18	17	2	11.8		
Matched controls	43	40	12	30.0		
Weighted data						
NovoSeven®	18	17	2	11.8	[-5.3 ; 28.8]	
Matched controls	18.0	17.2	5.3	30.6	[15.7 ; 45.5]	
Adjusted Odds ratio						
NovoSeven®/Matched controls				0.17	[0.00 ; 1.39]	0.1293

PS: Propensity score, PSAS: Propensity score analysis set, N: Number of (weighted) Patients used in analysis, n: Number of (weighted) patients having invasive procedure, CI: confidence interval.

Observed data is the raw proportion of events in each group. The weighted data is the proportion with 95% Wald's confidence interval in each group where the matched controls are weighted according to number of controls selected in the matching process to adjust for difference in number of controls across NovoSeven® exposed women. Odds ratio for Invasive procedures were compared between NovoSeven® and matched control based on an exact conditional logistic regression model with a 95% exact confidence interval based on the propensity score matching, along with p-value. Estimates and CIs for NovoSeven® and Matched control are presented in proportion/percentage.

Patient with hysterectomy in the period from time0 to time0+30 minutes are excluded from the PS analysis set (1 patients with NovoSeven® and 3 matched controls).

Two controls (■■■■, ■■■■) had an invasive procedure after 24 hours window are not considered in the primary analysis.

/fvii/nn7711-4729/ctr_20210821_er
18AUG2021:14:41:49 - tstatpeipsenlag30.sas/tstatpeipsenlag30psas.txt

14.2.24 Primary endpoint - invasive procedure - supplementary analysis 1 - Supplementary PS analysis set

	PSAS	N	n	Estimate	95% CI	p-value
Invasive Procedure						
Observed data						
NovoSeven®	18	11	0	0.0		
Matched controls	43	21	5	23.8		
Weighted data						
NovoSeven®	18	11	0	0.0	[0.0 ; 0.0]	
Matched controls	18.0	11.0	3.2	28.8	[7.7 ; 49.9]	
Adjusted Odds ratio						
NovoSeven®/Matched controls				0.22*	[0.00 ; 1.30]	0.1667

PS: Propensity score, PSAS: Propensity score analysis set, N: Number of (weighted) Patients used in analysis, n: Number of (weighted) patients having invasive procedure, CI: confidence interval.

Observed data is the raw proportion of events in each group. The weighted data is the proportion with 95% Wald's confidence interval in each group where the matched controls are weighted according to number of controls selected in the matching process to adjust for difference in number of controls across NovoSeven® exposed women. Odds ratio for invasive procedures were compared between NovoSeven® and matched control based on an exact conditional logistic regression model with a 95% exact confidence interval based on the propensity score matching, along with p-value. Patient with hysterectomy in the conjoint period are excluded from the PS analysis set (0 patients with NovoSeven® and 1 matched control).

* Indicates a median unbiased estimate.

The women that were selected as matched controls and later exposed to NovoSeven®, are excluded for supplementary analysis 1.

Two controls (■■■■, ■■■■) had an invasive procedure after 24 hours window are not considered in the primary analysis.

/fvii/nn7711-4729/ctr_20210821_er
18AUG2021:14:41:50 - tstatpeipsuppl.sas/tstatpeipsupplpsas.txt

14.2.25 Primary endpoint - invasive procedure - supplementary analysis 2 - Supplementary PS analysis set

	PSAS	N	n	Estimate	95% CI	p-value
Invasive Procedure						
Observed data						
NovoSeven®	18	18	4	22.2		
Matched controls	43	42	26	61.9		
Weighted data						
NovoSeven®	18	18	4	22.2	[0.9 ; 43.5]	
Matched controls	18.0	17.8	12.3	69.5	[55.0 ; 84.0]	
Adjusted Odds ratio						
NovoSeven®/Matched controls				0.07	[0.00 ; 0.49]	0.0019

PS: Propensity score, PSAS: Propensity score analysis set, N: Number of (weighted) Patients used in analysis, n: Number of (weighted) patients having invasive procedure, CI: confidence interval.

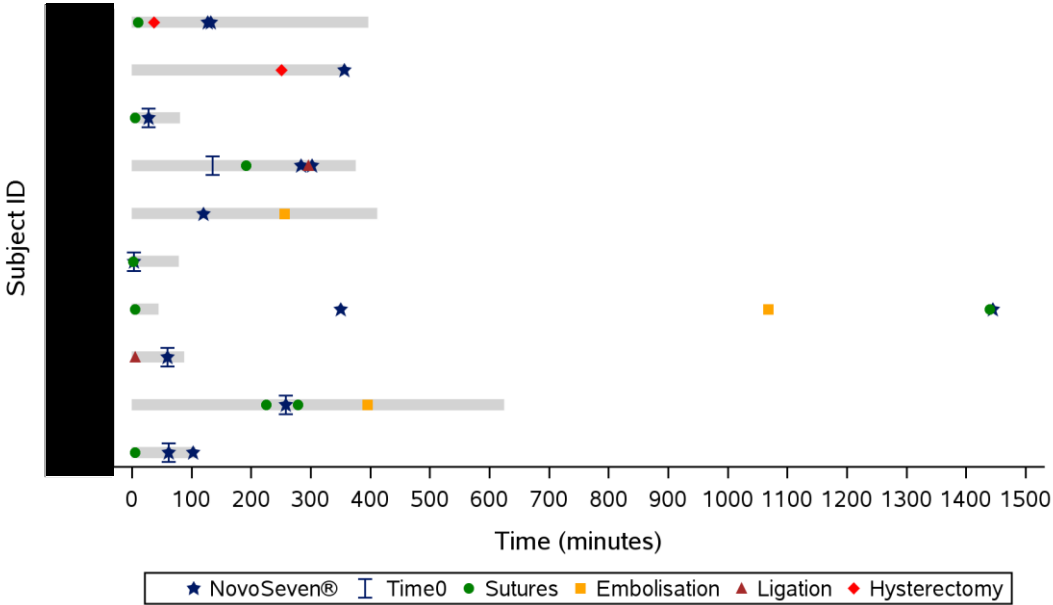
Observed data is the raw proportion of events in each group. The weighted data is the proportion with 95% Wald's confidence interval in each group where the matched controls are weighted according to number of controls selected in the matching process to adjust for difference in number of controls across NovoSeven® exposed women. Odds ratio for invasive procedures were compared between NovoSeven® and matched control based on an exact conditional logistic regression model with a 95% exact confidence interval based on the propensity score matching, along with p-value. Patient with hysterectomy in the conjoint period are excluded from the PS analysis set (0 patients with NovoSeven® and 1 matched control).

The women that were selected as matched controls and later exposed to NovoSeven®, are imputed to have had an invasive procedure at the time of the first NovoSeven® exposure and exposed women with additional doses are imputed to have an invasive procedure after time0 for supplementary analysis 2.

Two controls (■■■■, ■■■■) had an invasive procedure after 24 hours window are not considered in the primary analysis.

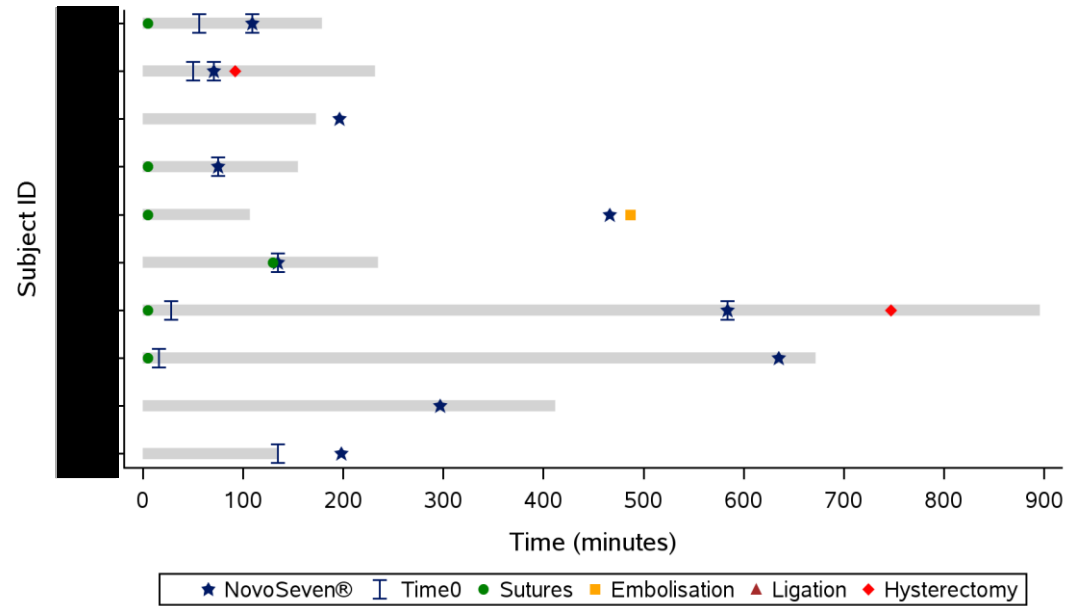
/fvii/nn7711-4729/ctr_20210821_er
18AUG2021:14:41:52 - tstatpeipsupp2.sas/tstatpeipsupp2psas.txt

14.2.26 Time from start sPPH to invasive procedures for patients exposed to NovoSeven® - Part1 - full analysis set



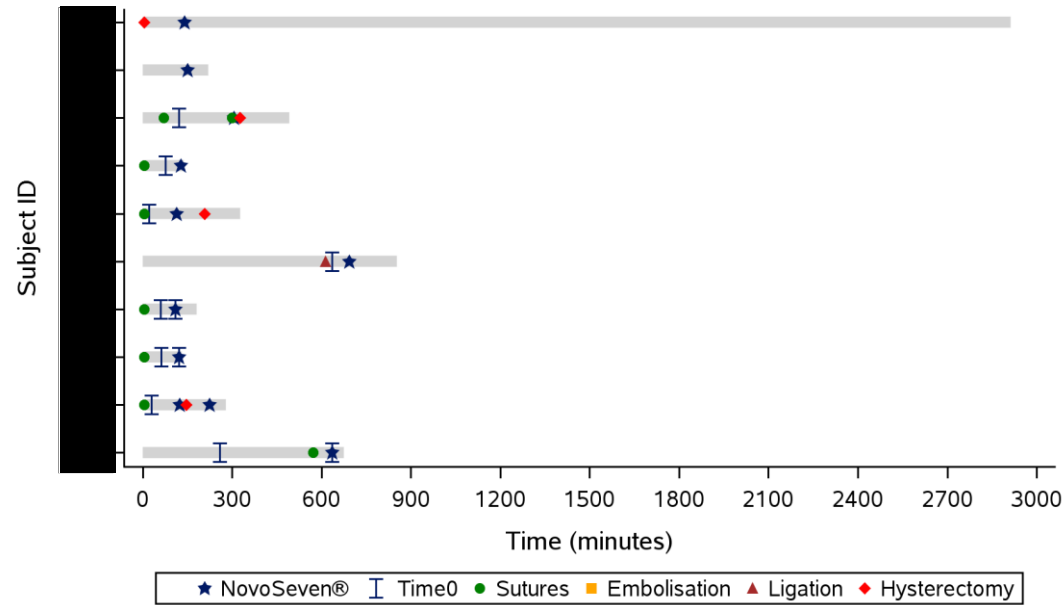
sPPH: Severe postpartum haemorrhage.
Horizontal bar represents the duration from severe PPH to PPH end.

14.2.27 Time from start sPPH to invasive procedures for patients exposed to NovoSeven® - Part2 - full analysis set



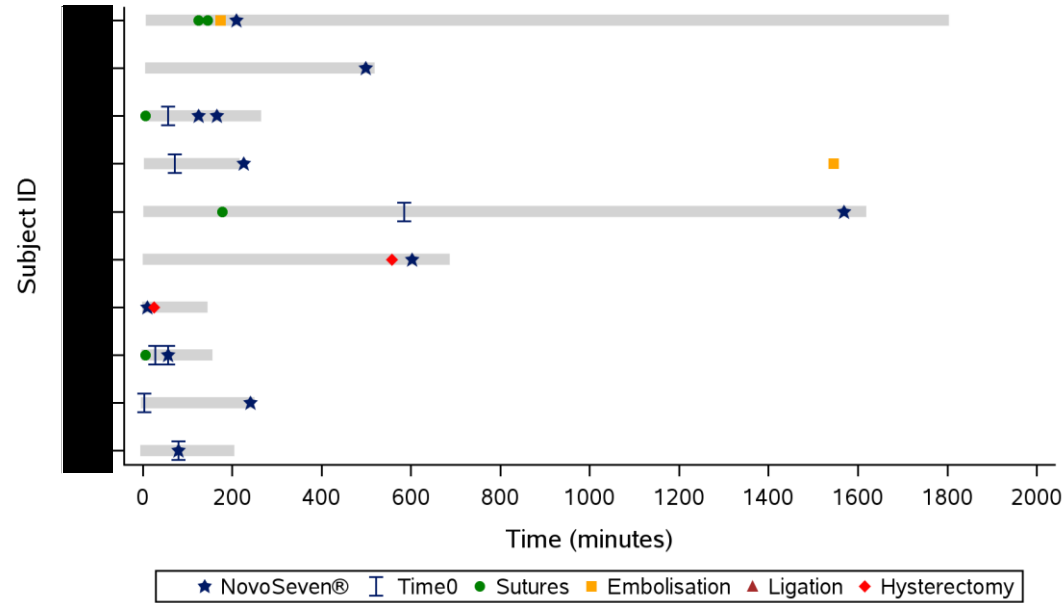
sPPH: Severe postpartum haemorrhage.
Horizontal bar represents the duration from severe PPH to PPH end.

14.2.28 Time from start sPPH to invasive procedures for patients exposed to NovoSeven® - Part3 - full analysis set



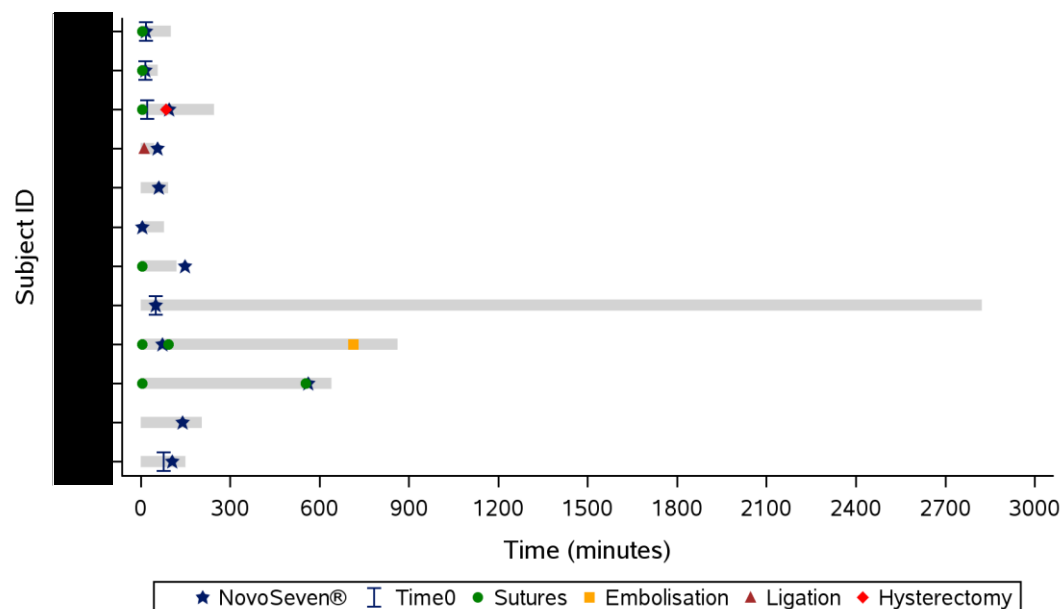
sPPH: Severe postpartum haemorrhage.
Horizontal bar represents the duration from severe PPH to PPH end.

14.2.29 Time from start sPPH to invasive procedures for patients exposed to NovoSeven® - Part4 - full analysis set



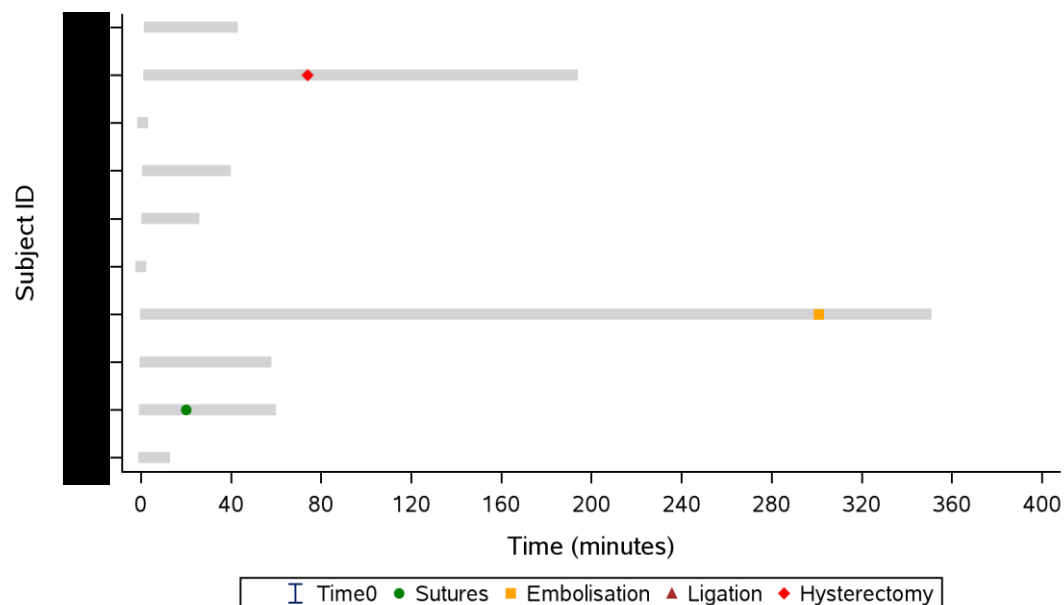
sPPH: Severe postpartum haemorrhage.
Horizontal bar represents the duration from severe PPH to PPH end.

14.2.30 Time from start sPPH to invasive procedures for patients exposed to NovoSeven® - Part5 - full analysis set



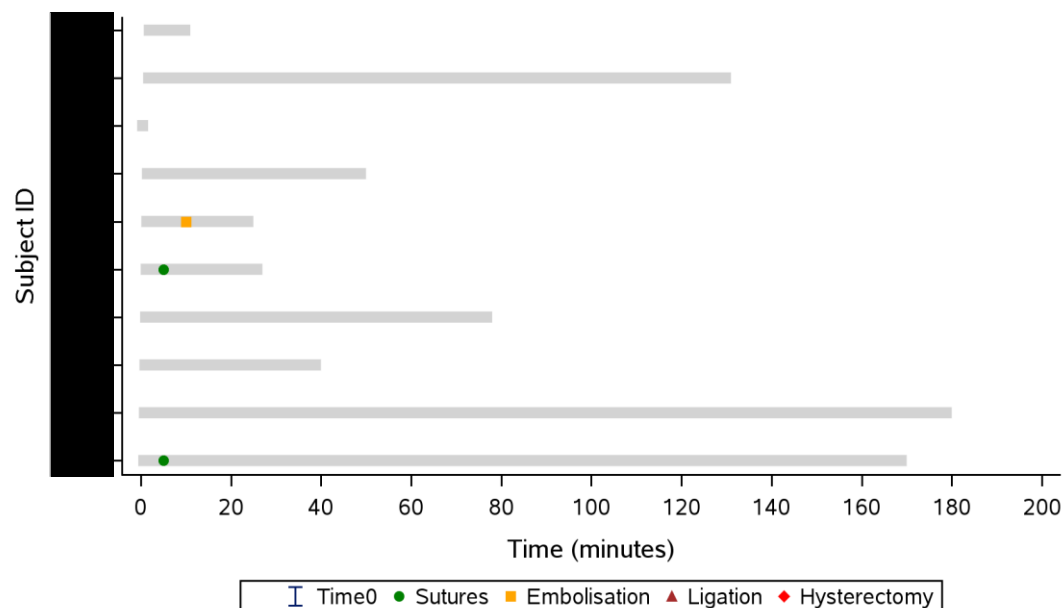
sPPH: Severe postpartum haemorrhage.
Horizontal bar represents the duration from severe PPH to PPH end.

14.2.31 Time from start sPPH to invasive procedures for patients without NovoSeven® - Part1 - full analysis set



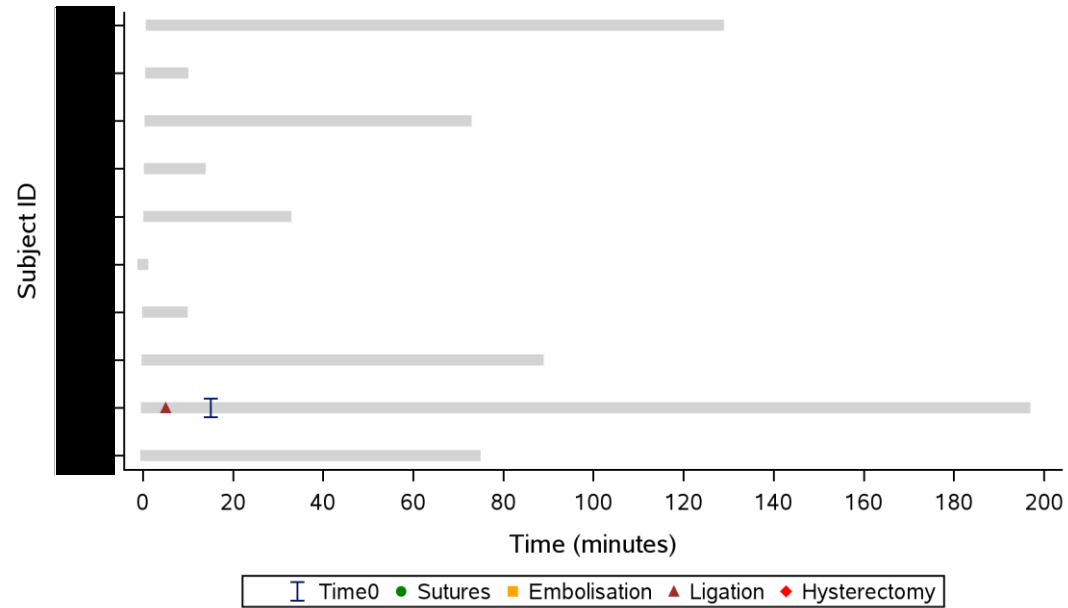
sPPH: Severe postpartum haemorrhage.
Horizontal bar represents the duration from severe PPH to PPH end.

14.2.32 Time from start sPPH to invasive procedures for patients without NovoSeven® - Part2 - full analysis set



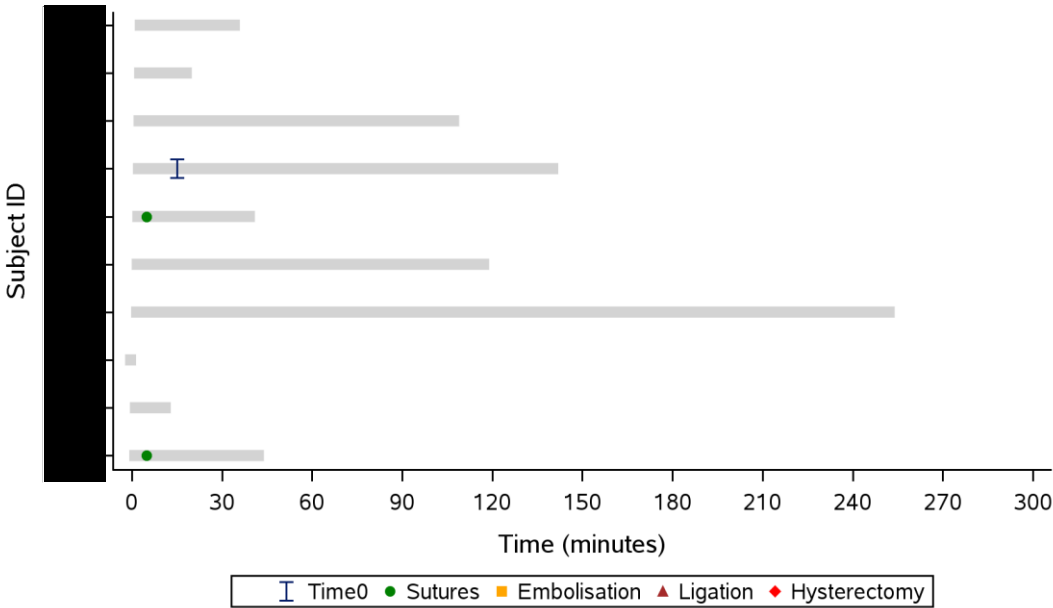
sPPH: Severe postpartum haemorrhage.
Horizontal bar represents the duration from severe PPH to PPH end.

14.2.33 Time from start sPPH to invasive procedures for patients without NovoSeven® - Part3 - full analysis set



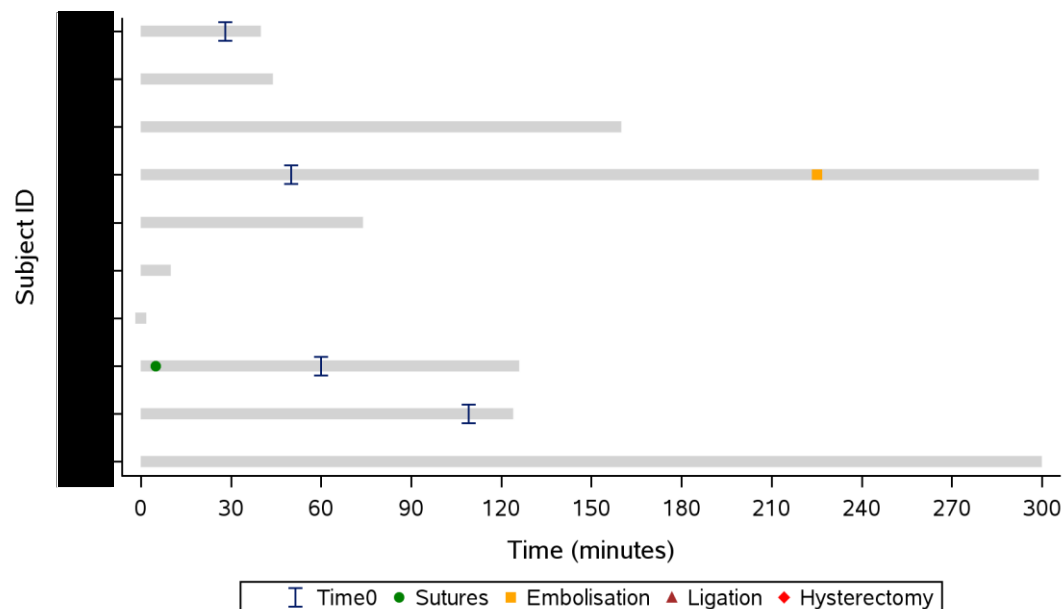
sPPH: Severe postpartum haemorrhage.
Horizontal bar represents the duration from severe PPH to PPH end.

14.2.34 Time from start sPPH to invasive procedures for patients without NovoSeven® - Part4 - full analysis set



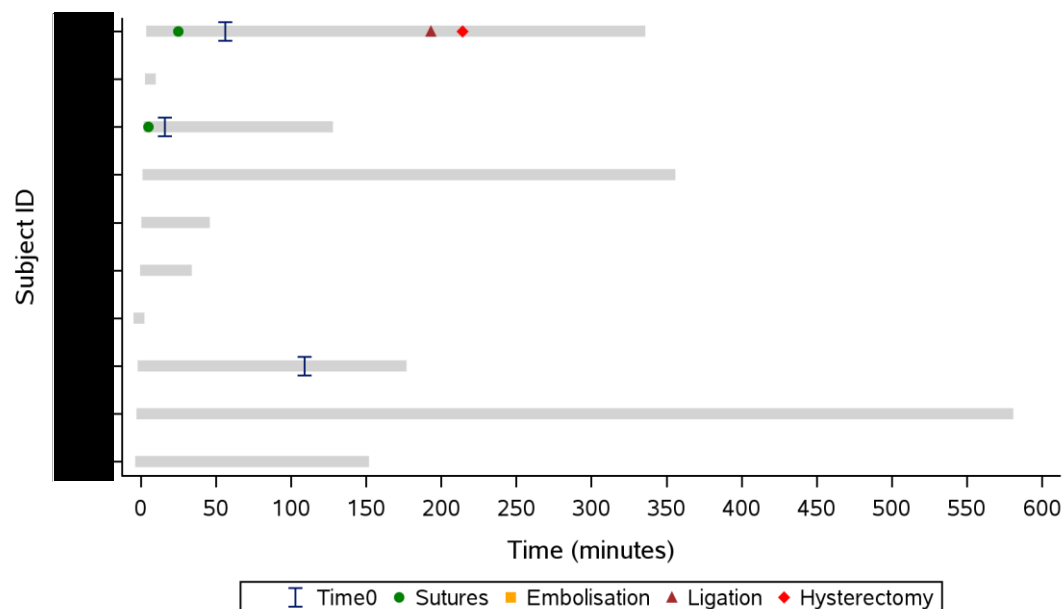
sPPH: Severe postpartum haemorrhage.
 Horizontal bar represents the duration from severe PPH to PPH end.

14.2.35 Time from start sPPH to invasive procedures for patients without NovoSeven® - Part5 - full analysis set



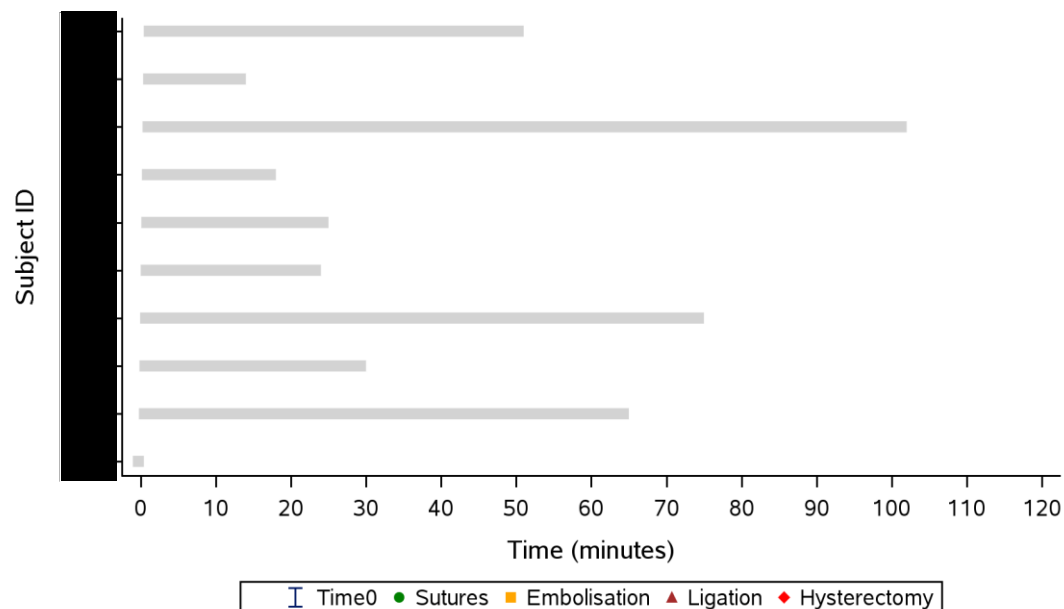
sPPH: Severe postpartum haemorrhage.
Horizontal bar represents the duration from severe PPH to PPH end.

14.2.36 Time from start sPPH to invasive procedures for patients without NovoSeven® - Part6 - full analysis set



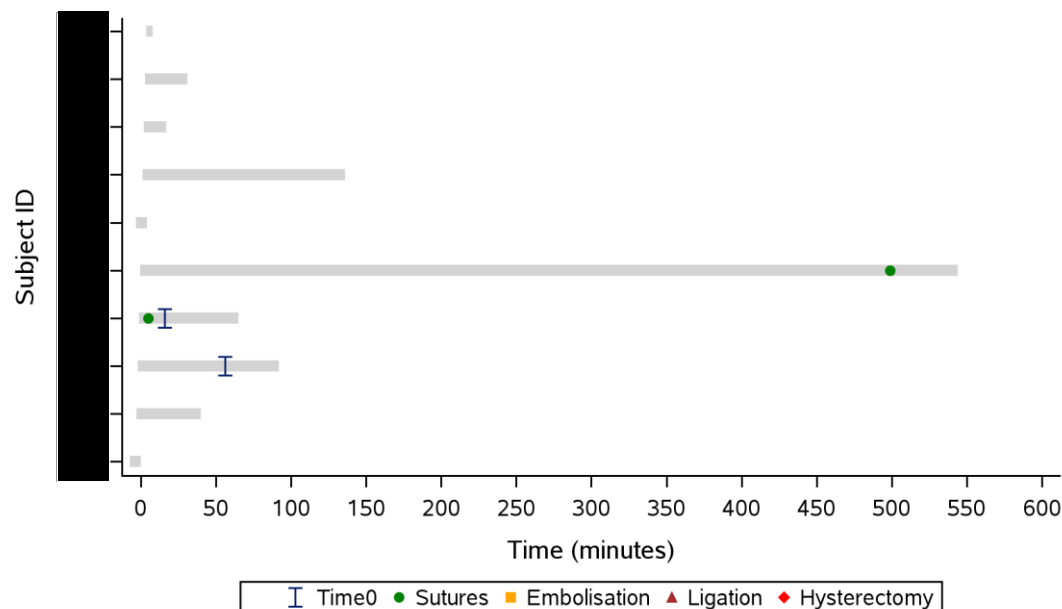
sPPH: Severe postpartum haemorrhage.
Horizontal bar represents the duration from severe PPH to PPH end.

14.2.37 Time from start sPPH to invasive procedures for patients without NovoSeven® - Part7 - full analysis set



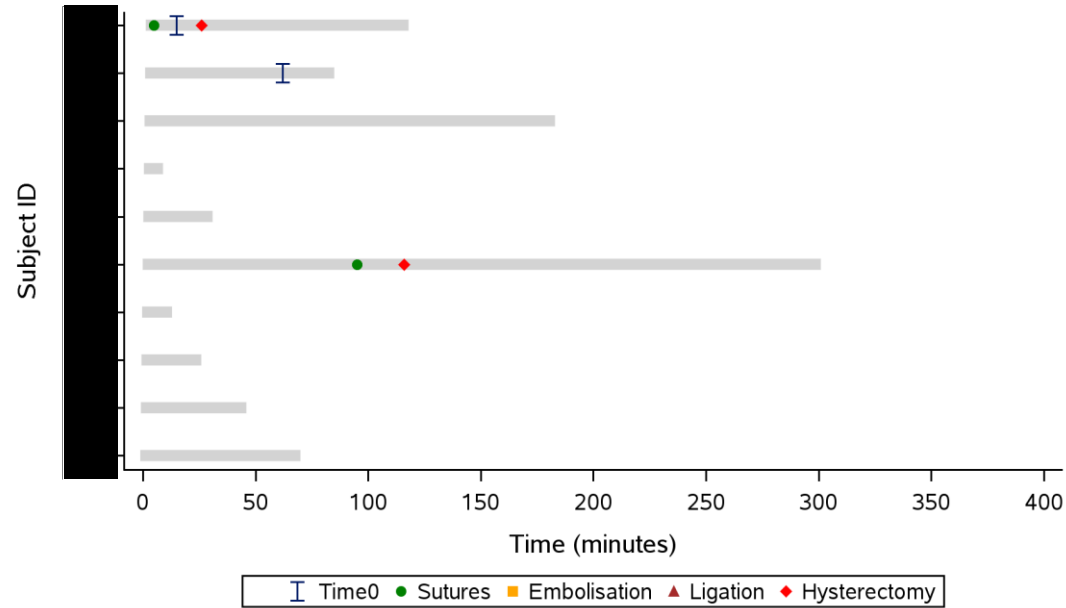
sPPH: Severe postpartum haemorrhage.
Horizontal bar represents the duration from severe PPH to PPH end.

14.2.38 Time from start sPPH to invasive procedures for patients without NovoSeven® - Part8 - full analysis set



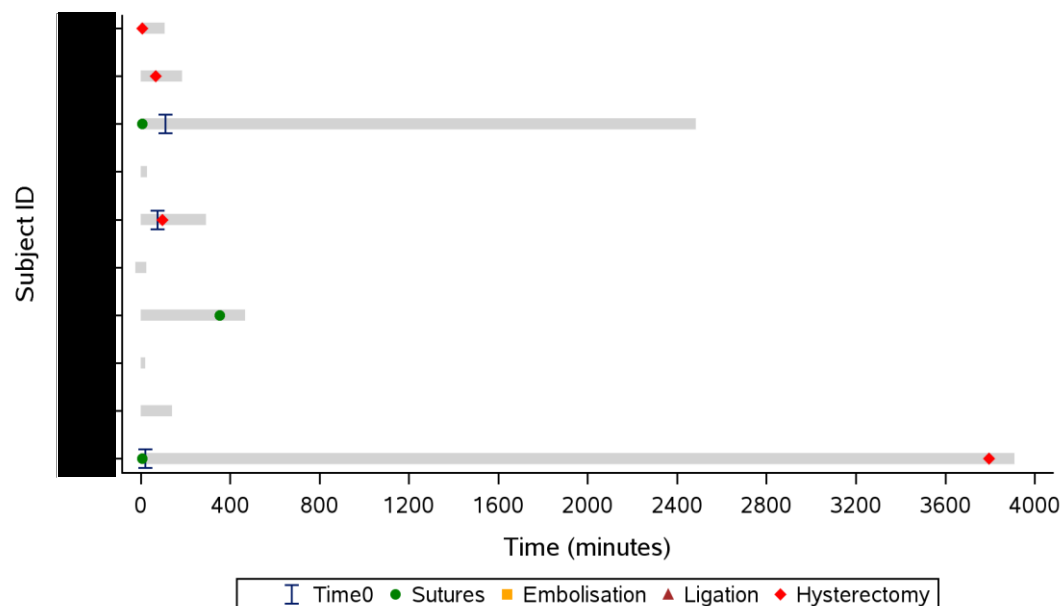
sPPH: Severe postpartum haemorrhage.
Horizontal bar represents the duration from severe PPH to PPH end.

14.2.39 Time from start sPPH to invasive procedures for patients without NovoSeven® - Part9 - full analysis set



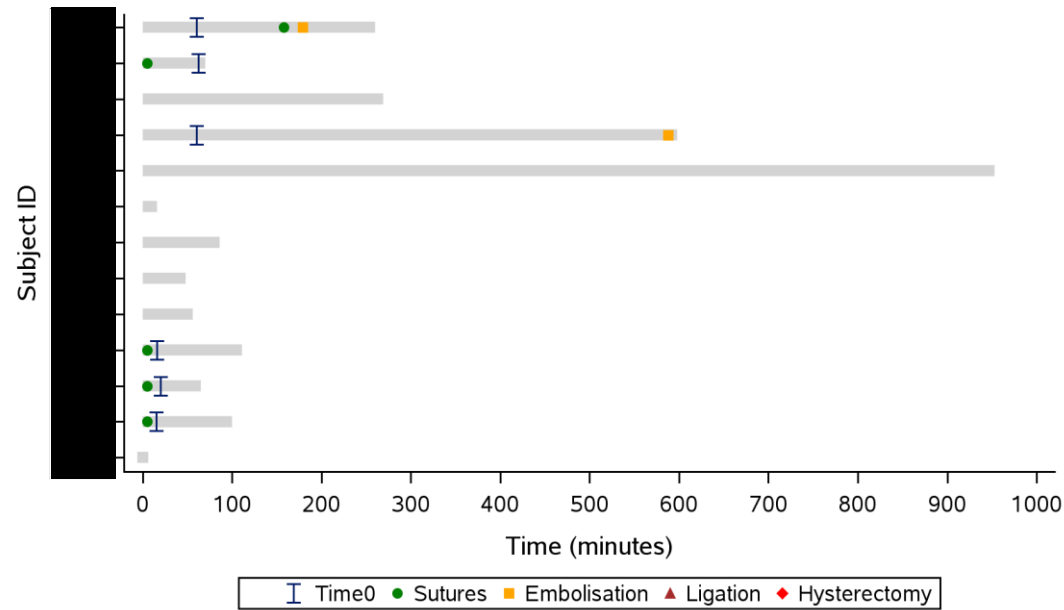
sPPH: Severe postpartum haemorrhage.
Horizontal bar represents the duration from severe PPH to PPH end.

14.2.40 Time from start sPPH to invasive procedures for patients without NovoSeven® - Part10 - full analysis set



sPPH: Severe postpartum haemorrhage.
Horizontal bar represents the duration from severe PPH to PPH end.

14.2.41 Time from start sPPH to invasive procedures for patients without NovoSeven® - Part11 - full analysis set



sPPH: Severe postpartum haemorrhage.
Horizontal bar represents the duration from severe PPH to PPH end.

14.2.42 Primary endpoint - Invasive procedures after onset of severe PPH by cohort - statistical analysis - full analysis set

	FAS	N	n	Proportion	95% CI
Cohort 1 (2006-2007)					
Invasive Procedure					
NovoSeven®	14	14	11	78.6	[49.2 ; 95.3]
No NovoSeven®	0	0	0		
Total	14	14	11	78.6	[49.2 ; 95.3]
Cohort 2 (2008-2010)					
Invasive Procedure					
NovoSeven®	15	15	12	80.0	[51.9 ; 95.7]
No NovoSeven®	12	12	7	58.3	[27.7 ; 84.8]
Total	27	27	19	70.4	[49.8 ; 86.2]
Cohort 3 (2010-2012)					
Invasive Procedure					
NovoSeven®	15	15	9	60.0	[32.3 ; 83.7]
No NovoSeven®	12	12	6	50.0	[21.1 ; 78.9]
Total	27	27	15	55.6	[35.3 ; 74.5]
Cohort 4 (2013-2016)					
Invasive Procedure					
NovoSeven®	8	8	8	100.0	[63.1 ; 100.0]
No NovoSeven®	89	89	16	18.0	[10.6 ; 27.5]
Total	97	97	24	24.7	[16.5 ; 34.5]

PPH: Postpartum haemorrhage, FAS: Full analysis set, N: Number of patients used in analysis, n: Number of patients having invasive procedure, CI: Exact binomial confidence interval.
Proportions and 95% CI are presented in percentage scale.
Invasive procedures are included regardless of timing of NovoSeven®.

14.2.43 Secondary and other endpoints - control of bleeding - blood products transfused - summary - PS analysis set

	NovoSeven®	Matched controls
Number of patients	18	43
RBC transfused before time0 (count)		
N	16	14.3
Mean (SD)	4.4 (2.9)	4.5 (1.7)
Median (IQR)	4.5 (2.0 - 6.0)	4.0 (2.0 - 6.0)
Min ; Max	1 ; 10	1 ; 10
RBC transfused upto 24 hours after time0 (count)		
N	15	16.4
Mean (SD)	7.1 (5.1)	8.1 (3.5)
Median (IQR)	6.0 (3.0 - 10.0)	7.0 (4.0 - 11.0)
Min ; Max	1 ; 20	1 ; 23
RBC transfused after time0 (count)		
N	15	17.4
Mean (SD)	7.3 (5.4)	7.9 (3.5)
Median (IQR)	6.0 (3.0 - 10.0)	6.0 (4.0 - 11.0)
Min ; Max	1 ; 20	1 ; 23
RBC transfused before time0 (mL)		
N	16	14.3
Mean (SD)	1220.3 (790.5)	1230.3 (479.9)
Median (IQR)	1237.5 (550.0 - 1650.0)	1100.0 (550.0 - 1650.0)
Min ; Max	275 ; 2750	275 ; 2750
RBC transfused upto 24 hours after time0 (mL)		
N	15	16.4
Mean (SD)	1961.7 (1401.7)	2219.5 (960.1)
Median (IQR)	1650.0 (825.0 - 2750.0)	1925.0 (1100.0 - 3025.0)
Min ; Max	275 ; 5500	275 ; 6325
RBC transfused after time0 (mL)		
N	15	17.4
Mean (SD)	2016.7 (1494.2)	2182.9 (960.2)
Median (IQR)	1650.0 (825.0 - 2750.0)	1650.0 (1100.0 - 3025.0)
Min ; Max	275 ; 5500	275 ; 6325

PS: Propensity score, RBC: Red blood cells, FFP: Fresh frozen plasma, N: Number of (weighted) patients, %: Percentage of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile).

NovoSeven®
Trial ID: NN7711-4729

Non-interventional report
Report body

Date:
Version:

02 September 2021
1.0

Status:
Page:

Final
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Novo Nordisk

Secondary and other endpoints - control of bleeding - blood products transfused - summary - PS analysis set

	NovoSeven®	Matched controls
FFP transfused before time0 (count)		
N	14	14.0
Mean (SD)	4.4 (3.0)	4.0 (1.7)
Median (IQR)	4.0 (2.0 - 6.0)	4.0 (3.0 - 4.0)
Min ; Max	1 ; 10	1 ; 10
FFP transfused upto 24 hours after time0 (count)		
N	17	14.3
Mean (SD)	5.9 (5.9)	7.2 (3.2)
Median (IQR)	4.0 (2.0 - 7.0)	7.0 (5.0 - 9.0)
Min ; Max	1 ; 23	1 ; 26
FFP transfused after time0 (count)		
N	17	15.3
Mean (SD)	5.9 (5.9)	7.0 (3.2)
Median (IQR)	4.0 (2.0 - 7.0)	7.0 (4.0 - 9.0)
Min ; Max	1 ; 23	1 ; 26
FFP transfused before time0 (mL)		
N	14	14.0
Mean (SD)	1240.0 (834.3)	1131.7 (484.6)
Median (IQR)	1120.0 (560.0 - 1680.0)	1120.0 (840.0 - 1120.0)
Min ; Max	280 ; 2800	280 ; 2800
FFP transfused upto 24 hours after time0 (mL)		
N	17	14.3
Mean (SD)	1647.1 (1656.2)	2015.7 (899.3)
Median (IQR)	1120.0 (560.0 - 1960.0)	1960.0 (1400.0 - 2520.0)
Min ; Max	280 ; 6440	280 ; 7280
FFP transfused after time0 (mL)		
N	17	15.3
Mean (SD)	1647.1 (1656.2)	1970.7 (889.6)
Median (IQR)	1120.0 (560.0 - 1960.0)	1960.0 (1120.0 - 2520.0)
Min ; Max	280 ; 6440	280 ; 7280

PS: Propensity score, RBC: Red blood cells, FFP: Fresh frozen plasma, N: Number of (weighted) patients, %: Percentage of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile).

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Secondary and other endpoints - control of bleeding - blood products transfused - summary - PS analysis set

	NovoSeven®	Matched controls
Platelets transfused before time0 (count)		
N	4	3.5
Mean (SD)	1.0 (0.0)	1.0 (0.0)
Median (IQR)	1.0 (1.0 - 1.0)	1.0 (1.0 - 1.0)
Min ; Max	1 ; 1	1 ; 1
Platelets transfused upto 24 hours after time0 (count)		
N	8	9.7
Mean (SD)	1.5 (0.8)	2.0 (0.6)
Median (IQR)	1.0 (1.0 - 2.0)	2.0 (1.0 - 3.0)
Min ; Max	1 ; 3	1 ; 3
Platelets transfused after time0 (count)		
N	8	9.7
Mean (SD)	1.5 (0.8)	2.0 (0.6)
Median (IQR)	1.0 (1.0 - 2.0)	2.0 (1.0 - 3.0)
Min ; Max	1 ; 3	1 ; 3
Platelets transfused before time0 (mL)		
N	4	3.5
Mean (SD)	125.0 (0.0)	125.0 (0.0)
Median (IQR)	125.0 (125.0 - 125.0)	125.0 (125.0 - 125.0)
Min ; Max	125 ; 125	125 ; 125
Platelets transfused upto 24 hours after time0 (mL)		
N	8	9.7
Mean (SD)	187.5 (94.5)	247.8 (74.0)
Median (IQR)	125.0 (125.0 - 250.0)	250.0 (125.0 - 375.0)
Min ; Max	125 ; 375	125 ; 375
Platelets transfused after time0 (mL)		
N	8	9.7
Mean (SD)	187.5 (94.5)	247.8 (74.0)
Median (IQR)	125.0 (125.0 - 250.0)	250.0 (125.0 - 375.0)
Min ; Max	125 ; 375	125 ; 375

PS: Propensity score, RBC: Red blood cells, FFP: Fresh frozen plasma, N: Number of (weighted) patients, %: Percentage of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile).

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14.2.44 Secondary endpoint - control of bleeding - estimated blood loss - summary - full analysis set

PS Analysis set		
	NovoSeven®	Matched controls
Number of patients	18	43
Estimated total blood loss (mL)		
N	18	18.0
Mean (SD)	4450.0 (1638.6)	4309.3 (1207.3)
Median (IQR)	4550.0 (3500.0 - 5500.0)	4100.0 (2900.0 - 5600.0)
Min ; Max	1500 ; 7500	1500 ; 7500

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile).
Total blood loss throughout the event.

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Secondary endpoint - control of bleeding - estimated blood loss - summary - full analysis set

Full analysis set			
	NovoSeven®	No NovoSeven®	Total
1.0 Number of patients	52	113	165
Estimated total blood loss (mL)			
N	52	113	165
Mean (SD)	4962.5 (2060.6)	2351.3 (1090.9)	3174.2 (1901.0)
Median (IQR)	4500.0 (4000.0 - 6000.0)	2000.0 (1500.0 - 2800.0)	2500.0 (1600.0 - 4000.0)
Min ; Max	1500 ; 12000	1500 ; 7000	1500 ; 12000

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile).

Total blood loss throughout the event.

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14.2.45 Secondary endpoint - control of bleeding - blood products transfused - statistical analysis - PS analysis set

	PSAS	N	Estimate	SE	95% CI	p-value
RBC transfusions after time0 (rate as units per hour)						
NovoSeven®	18	18	0.22	0.21	[0.14 ; 0.34]	
Matched controls	43	43	0.26	0.17	[0.18 ; 0.36]	
NovoSeven®/Matched controls	61	61	0.86	0.22	[0.56 ; 1.33]	0.4849
RBC transfusions (rate as units per hour)						
NovoSeven®: Before time0	18	18	1.23	0.22	[0.79 ; 1.92]	
NovoSeven®: After time0	18	18	0.24	0.20	[0.16 ; 0.36]	
NovoSeven® reduction: after/before	18	18	0.19	0.29	[0.11 ; 0.34]	
Matched controls: Before time0	43	43	0.81	0.17	[0.58 ; 1.14]	
Matched controls: After time0	43	43	0.27	0.14	[0.20 ; 0.36]	
Matched controls reduction: after/before	43	43	0.33	0.20	[0.22 ; 0.49]	
NovoSeven®/Matched controls ratio of reductions after time0	61	61	0.58	0.35	[0.29 ; 1.17]	0.1253

PS: Propensity score, PSAS: Propensity score analysis set, RBC: Red blood cells, FFP: Fresh frozen plasma, N: Number of patients used in analysis, SE: Standard error on log scale, CI: confidence interval.

For transfusions after time0, post time0 count is analysed using negative binomial regression with treatment as factor, the pre-count divided by the duration of the pre-period as covariate, matched groups are included as a random effect and (log)duration of after time0 period as an offset.

For transfusions before/ after time0 and relative reductions, a negative binomial regression is performed with treatment, period (before/after time0), the interaction between treatment and period as factors. Patients and matched groups are included as a random effect and (log)duration of each period is included as an offset.

Newton-Raphson technique is used to achieve convergence.

Analysis duration is from delivery to 24 hours after time0.

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Secondary endpoint - control of bleeding - blood products transfused - statistical analysis - PS analysis set

	PSAS	N	Estimate	SE	95% CI	p-value
FFP transfusions after time0 (rate as units per hour)						
NovoSeven®	18	18	0.19	0.25	[0.11 ; 0.31]	
Matched controls	43	43	0.20	0.19	[0.14 ; 0.29]	
NovoSeven®/Matched controls	61	61	0.93	0.26	[0.54 ; 1.58]	0.7763
FFP transfusions (rate as units per hour)						
NovoSeven®: Before time0	18	18	1.03	0.25	[0.63 ; 1.69]	
NovoSeven®: After time0	18	18	0.22	0.22	[0.14 ; 0.35]	
NovoSeven® reduction: after/before	18	18	0.21	0.32	[0.11 ; 0.40]	
Matched controls: Before time0	43	43	0.61	0.19	[0.41 ; 0.89]	
Matched controls: After time0	43	43	0.21	0.16	[0.15 ; 0.29]	
Matched controls reduction: after/before	43	43	0.35	0.22	[0.22 ; 0.55]	
NovoSeven®/Matched controls ratio of reductions after time0	61	61	0.61	0.39	[0.28 ; 1.32]	0.2044

PS: Propensity score, PSAS: Propensity score analysis set, RBC: Red blood cells, FFP: Fresh frozen plasma, N: Number of patients used in analysis, SE: Standard error on log scale, CI: confidence interval.

For transfusions after time0, post time0 count is analysed using negative binomial regression with treatment as factor, the pre-count divided by the duration of the pre-period as covariate, matched groups are included as a random effect and (log)duration of after time0 period as an offset.

For transfusions before/ after time0 and relative reductions, a negative binomial regression is performed with treatment, period (before/after time0), the interaction between treatment and period as factors. Patients and matched groups are included as a random effect and (log)duration of each period is included as an offset.

Newton-Raphson technique is used to achieve convergence.

Analysis duration is from delivery to 24 hours after time0.

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14.2.46 Secondary endpoint - control of bleeding - blood products transfused - supportive statistical analysis - PS analysis set

	PSAS	N	Estimate	SE	95% CI	p-value
RBC transfusions after time0 (rate as units per hour)						
NovoSeven®	18	18	0.22	0.21	[0.14 ; 0.33]	
Matched controls	43	43	0.26	0.17	[0.18 ; 0.36]	
NovoSeven®/Matched controls	61	61	0.84	0.21	[0.55 ; 1.28]	0.4013
RBC transfusions (rate as units per hour)						
NovoSeven®: Before time0	18	18	1.41	0.22	[0.90 ; 2.21]	
NovoSeven®: After time0	18	18	0.23	0.21	[0.15 ; 0.35]	
NovoSeven® reduction: after/before	18	18	0.16	0.28	[0.09 ; 0.29]	
Matched controls: Before time0	43	43	1.04	0.18	[0.73 ; 1.47]	
Matched controls: After time0	43	43	0.27	0.16	[0.20 ; 0.37]	
Matched controls reduction: after/before	43	43	0.26	0.19	[0.18 ; 0.39]	
NovoSeven®/Matched controls ratio of reductions after time0	61	61	0.62	0.34	[0.31 ; 1.22]	0.1611

PS: Propensity score, PSAS: Propensity score analysis set, RBC: Red blood cells, FFP: Fresh frozen plasma, N: Number of patients used in analysis, SE: Standard error on log scale, CI: confidence interval.

For transfusions after time0, post time0 count is analysed using negative binomial regression with treatment as factor, the pre-count divided by the duration of the pre-period as covariate, matched groups are included as a random effect and (log)duration of after time0 period as an offset.

For transfusions before/ after time0 and relative reductions, a negative binomial regression is performed with treatment, period (before/after time0), the interaction between treatment and period as factors. Patients and matched groups are included as a random effect and (log)duration of each period is included as an offset.

Newton-Raphson technique is used to achieve convergence.

Analysis duration is from onset of PPH to 24 hours after time0.

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Secondary endpoint - control of bleeding - blood products transfused - supportive statistical analysis - PS analysis set

	PSAS	N	Estimate	SE	95% CI	p-value
FFP transfusions after time0 (rate as units per hour)						
NovoSeven®	18	18	0.18	0.23	[0.11 ; 0.29]	
Matched controls	43	43	0.19	0.19	[0.13 ; 0.28]	
NovoSeven®/Matched controls	61	61	0.95	0.23	[0.59 ; 1.53]	0.8445
FFP transfusions (rate as units per hour)						
NovoSeven®: Before time0	18	18	1.17	0.25	[0.70 ; 1.93]	
NovoSeven®: After time0	18	18	0.21	0.23	[0.13 ; 0.34]	
NovoSeven® reduction: after/before	18	18	0.18	0.31	[0.10 ; 0.34]	
Matched controls: Before time0	43	43	0.82	0.20	[0.55 ; 1.22]	
Matched controls: After time0	43	43	0.22	0.17	[0.15 ; 0.31]	
Matched controls reduction: after/before	43	43	0.26	0.22	[0.17 ; 0.41]	
NovoSeven®/Matched controls ratio of reductions after time0	61	61	0.68	0.38	[0.32 ; 1.46]	0.3223

PS: Propensity score, PSAS: Propensity score analysis set, RBC: Red blood cells, FFP: Fresh frozen plasma, N: Number of patients used in analysis, SE: Standard error on log scale, CI: confidence interval.

For transfusions after time0, post time0 count is analysed using negative binomial regression with treatment as factor, the pre-count divided by the duration of the pre-period as covariate, matched groups are included as a random effect and (log)duration of after time0 period as an offset.

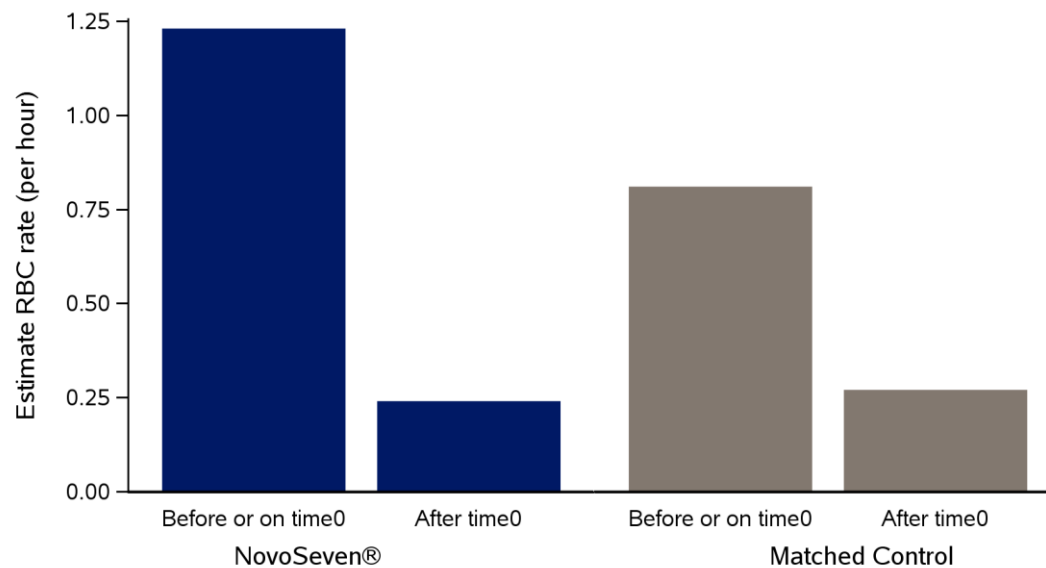
For transfusions before/ after time0 and relative reductions, a negative binomial regression is performed with treatment, period (before/after time0), the interaction between treatment and period as factors. Patients and matched groups are included as a random effect and (log)duration of each period is included as an offset.

Newton-Raphson technique is used to achieve convergence.

Analysis duration is from onset of PPH to 24 hours after time0.

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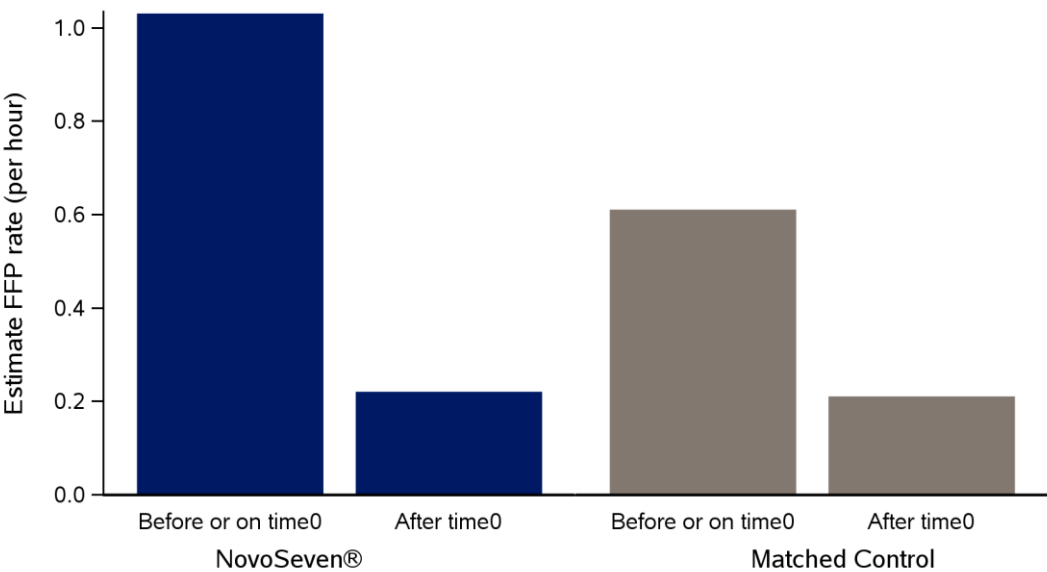
14.2.47 Secondary endpoint - control of bleeding - blood products transfused - RBC - bar plot - PS analysis set



PS: Propensity score, RBC: Red blood cells.
Analysis duration is from delivery and 24hours after time0.

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14.2.48 Secondary endpoint - control of bleeding - blood products transfused - FFP - bar plot - PS analysis set



PS: Propensity score, FFP: Fresh frozen plasma.
Analysis duration is from delivery and 24hours after time0.

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14.2.49 Secondary endpoint - control of bleeding - estimated blood loss - statistical analysis - PS analysis set

PSAS	N	Estimate	SE	95% CI	p-value

Insufficient data to report

PS: Propensity score, PSAS: Propensity score analysis set, N: Number of (weighted) Patients used in analysis, SE: Standard error, CI: confidence interval.
A log-linear regression model is performed with treatment, period (before/after time0), the interaction between treatment and period as factors. The propensity score and (log)duration of each period will be included as covariates in the model. Subject will be included as a random effect.

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14.2.50 Control of bleeding - full analysis set

	PS analysis set		Full analysis set		
	NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total
1.0 Number of patients	18	43	52	113	165
Number of weighted patients, N		18.0			
Duration from onset of sPPH to administration of first TXA (minutes)					
N	12	12.6	33	63	96
Mean (SD)	44.3 (37.5)	272.4 (308.2)	173.2 (290.6)	91.0 (241.6)	119.3 (260.9)
Median (IQR)	30.0 (13.0 - 73.0)	111.0 (21.0 - 165.0)	100.0 (29.0 - 165.0)	26.0 (8.0 - 56.0)	30.0 (13.5 - 112.0)
Min ; Max	2 ; 111	4 ; 1685	2 ; 1549	1 ; 1685	1 ; 1685
Duration from onset of sPPH to administration of first Fibrinogen (minutes)					
N	8	6.2	21	28	49
Mean (SD)	68.5 (69.4)	102.0 (45.6)	116.1 (132.5)	196.5 (290.4)	162.0 (237.4)
Median (IQR)	46.0 (31.0 - 74.0)	95.0 (44.0 - 137.0)	72.0 (42.0 - 110.0)	95.5 (48.0 - 195.0)	82.0 (44.0 - 156.0)
Min ; Max	16 ; 230	10 ; 368	16 ; 572	10 ; 1480	10 ; 1480
Duration from onset of sPPH to first NovoSeven® (minutes)					
N	18	0	52		
Mean (SD)	137.1 (181.6)		228.2 (266.6)		
Median (IQR)	73.0 (50.0 - 121.0)		127.5 (71.0 - 290.5)		
Min ; Max	3 ; 635		3 ; 1569		
Duration from onset of sPPH to stop of PPH (minutes)					
N	18	18.0	52	101	153
Mean (SD)	389.2 (651.6)	551.2 (475.4)	447.3 (604.8)	182.0 (466.8)	272.2 (531.0)
Median (IQR)	167.5 (101.0 - 235.0)	250.0 (138.0 - 673.5)	226.0 (133.0 - 505.5)	70.0 (31.0 - 152.0)	118.0 (45.0 - 254.0)
Min ; Max	57 ; 2823	40 ; 3910	45 ; 2913	8 ; 3910	8 ; 3910

PS: Propensity score, sPPH: Severe postpartum haemorrhage, TXA: Tranexamic acid, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), PPH: Postpartum haemorrhage.

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14.2.51 Control of bleeding - by concomitant use for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	7	7	1	3
Duration from onset of sPPH to administration of first TXA (minutes)				
N	6	6	0	0
Mean (SD)	14.8 (11.4)	73.7 (29.7)		
Median (IQR)	13.0 (5.0 - 25.0)	73.0 (56.0 - 100.0)		
Min ; Max	2 ; 31	29 ; 111		
Duration from onset of sPPH to administration of first Fibrinogen (minutes)				
N	7	0	1	0
Mean (SD)	64.7 (74.0)		95.0 (NE)	
Median (IQR)	42.0 (27.0 - 53.0)		95.0 (95.0 - 95.0)	
Min ; Max	16 ; 230		95 ; 95	
Duration from onset of sPPH to first NovoSeven® (minutes)				
N	7	7	1	3
Mean (SD)	66.3 (87.8)	77.1 (31.2)	635.0 (NE)	276.0 (267.1)
Median (IQR)	50.0 (15.0 - 62.0)	75.0 (56.0 - 109.0)	635.0 (635.0 - 635.0)	135.0 (109.0 - 584.0)
Min ; Max	3 ; 258	28 ; 121	635 ; 635	109 ; 584
Duration from onset of sPPH to stop of PPH (minutes)				
N	7	7	1	3
Mean (SD)	554.3 (1020.5)	162.7 (49.4)	675.0 (NE)	437.3 (398.1)
Median (IQR)	101.0 (79.0 - 625.0)	156.0 (131.0 - 205.0)	675.0 (675.0 - 675.0)	235.0 (181.0 - 896.0)
Min ; Max	57 ; 2823	81 ; 232	675 ; 675	181 ; 896

PS: Propensity score, sPPH: Severe postpartum haemorrhage, TXA: Tranexamic acid, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), PPH: Postpartum haemorrhage.
Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(≤)/after(>) time0.

14.2.52 Control of bleeding - by concomitant use for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	16	18	1	8
Number of weighted patients, N	5.2	8.8	1.0	3.1
Duration from onset of sPPH to administration of first TXA (minutes)				
N	4.4	7.9	0	0.3
Mean (SD)	51.3 (31.7)	351.1 (375.8)		1685.0 (NE)
Median (IQR)	24.0 (10.0 - 75.0)	165.0 (29.0 - 692.0)		1685.0 (1685.0 - 1685.0)
Min ; Max	5 ; 167	4 ; 1549		1685 ; 1685
Duration from onset of sPPH to administration of first Fibrinogen (minutes)				
N	5.2	0	1.0	0
Mean (SD)	103.3 (47.1)		95.0 (NE)	
Median (IQR)	86.5 (44.0 - 144.0)		95.0 (95.0 - 95.0)	
Min ; Max	10 ; 368		95 ; 95	
Duration from onset of sPPH to first NovoSeven® (minutes)				
N	0	0	0	0
Mean (SD)				
Median (IQR)				
Min ; Max				
Duration from onset of sPPH to stop of PPH (minutes)				
N	5.2	8.8	1.0	3.1
Mean (SD)	219.0 (76.3)	687.4 (574.4)	675.0 (NE)	681.4 (654.1)
Median (IQR)	177.0 (124.0 - 299.0)	250.0 (142.0 - 853.0)	675.0 (675.0 - 675.0)	492.0 (181.0 - 492.0)
Min ; Max	40 ; 598	65 ; 2484	675 ; 675	118 ; 3910

PS: Propensity score, sPPH: Severe postpartum haemorrhage, TXA: Tranexamic acid, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), PPH: Postpartum haemorrhage.
Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=)/after(>) time0.

14.2.53 Control of bleeding - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony
Number of patients	4	1	0	13
Duration from onset of sPPH to administration of first TXA (minutes)				
N	4	0	0	8
Mean (SD)	36.8 (51.0)			48.0 (32.3)
Median (IQR)	17.0 (3.5 - 70.0)			43.5 (20.5 - 73.0)
Min ; Max	2 ; 111			10 ; 100
Duration from onset of sPPH to administration of first Fibrinogen (minutes)				
N	2	1	0	5
Mean (SD)	136.0 (132.9)	27.0 (NE)		49.8 (29.2)
Median (IQR)	136.0 (42.0 - 230.0)	27.0 (27.0 - 27.0)		50.0 (35.0 - 53.0)
Min ; Max	42 ; 230	27 ; 27		16 ; 95
Duration from onset of sPPH to first NovoSeven® (minutes)				
N	4	1	0	13
Mean (SD)	76.0 (31.2)	3.0 (NE)		166.2 (207.0)
Median (IQR)	66.5 (56.0 - 96.0)	3.0 (3.0 - 3.0)		80.0 (56.0 - 135.0)
Min ; Max	50 ; 121	3 ; 3		15 ; 635
Duration from onset of sPPH to stop of PPH (minutes)				
N	4	1	0	13
Mean (SD)	823.3 (1334.3)	79.0 (NE)		279.5 (269.5)
Median (IQR)	181.5 (119.0 - 1527.5)	79.0 (79.0 - 79.0)		179.0 (101.0 - 235.0)
Min ; Max	107 ; 2823	79 ; 79		57 ; 896

PPH: Postpartum haemorrhage, AIP: Abnormally invasive placenta (including praevia), sPPH: Severe postpartum haemorrhage, PS: Propensity score, TXA: Tranexamic acid, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile).
 18AUG2021:14:42:13 - tsumcbleed.sas/tsumcbleedpphreanspsas.txt

Control of bleeding - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	Trauma	Other
Number of patients	0	0
Duration from onset of sPPH to administration of first TXA (minutes)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Duration from onset of sPPH to administration of first Fibrinogen (minutes)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Duration from onset of sPPH to first NovoSeven® (minutes)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Duration from onset of sPPH to stop of PPH (minutes)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, AIP: Abnormally invasive placenta (including praevia), sPPH: Severe postpartum haemorrhage, PS: Propensity score, TXA: Tranexamic acid, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile).
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14.2.54 Control of bleeding - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony
Number of patients	14	3	0	23
Number of weighted patients, N	5.0	2.3	0	8.4
Duration from onset of sPPH to administration of first TXA (minutes)				
N	4.0	2.3	0	4.3
Mean (SD)	133.9 (268.3)	383.9 (295.5)		72.6 (29.7)
Median (IQR)	8.0 (4.5 - 29.0)	165.0 (165.0 - 692.0)		56.0 (21.0 - 120.0)
Min ; Max	4 ; 1685	27 ; 692		5 ; 167
Duration from onset of sPPH to administration of first Fibrinogen (minutes)				
N	1.6	0.3	0	4.3
Mean (SD)	98.2 (76.4)	137.0 (NE)		101.3 (31.0)
Median (IQR)	44.0 (10.0 - 109.0)	137.0 (137.0 - 137.0)		95.0 (70.0 - 144.0)
Min ; Max	10 ; 368	137 ; 137		15 ; 182
Duration from onset of sPPH to first NovoSeven® (minutes)				
N	0	0	0	0
Mean (SD)				
Median (IQR)				
Min ; Max				
Duration from onset of sPPH to stop of PPH (minutes)				
N	5.0	2.3	0	8.4
Mean (SD)	845.1 (714.7)	504.2 (333.2)		321.2 (137.7)
Median (IQR)	239.0 (131.0 - 1541.0)	250.0 (250.0 - 853.0)		265.0 (135.0 - 492.0)
Min ; Max	65 ; 3910	126 ; 853		40 ; 896

PPH: Postpartum haemorrhage, AIP: Abnormally invasive placenta (including praevia), sPPH: Severe postpartum haemorrhage, PS: Propensity score, TXA: Tranexamic acid, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile).

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Control of bleeding - by cause of PPH for matched controls - PS analysis set

	Trauma	Other
Number of patients	2	1
Number of weighted patients, N	1.3	1.0
Duration from onset of sPPH to administration of first TXA (minutes)		
N	1.0	1.0
Mean (SD)	165.0 (NE)	1549.0 (NE)
Median (IQR)	165.0 (165.0 - 165.0)	1549.0 (1549.0 - 1549.0)
Min ; Max	165 ; 165	1549 ; 1549
Duration from onset of sPPH to administration of first Fibrinogen (minutes)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Duration from onset of sPPH to first NovoSeven® (minutes)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Duration from onset of sPPH to stop of PPH (minutes)		
N	1.3	1.0
Mean (SD)	180.3 (73.5)	1619.0 (NE)
Median (IQR)	217.0 (143.5 - 217.0)	1619.0 (1619.0 - 1619.0)
Min ; Max	70 ; 217	1619 ; 1619

PPH: Postpartum haemorrhage, AIP: Abnormally invasive placenta (including praevia), sPPH: Severe postpartum haemorrhage, PS: Propensity score, TXA: Tranexamic acid, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile).

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14.2.55 Control of bleeding - by timing of first NovoSeven® dose from invasive procedure - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
Number of patients	2	0	15
Duration from onset of sPPH to administration of first TXA (minutes)			
N	2	0	10
Mean (SD)	52.5 (67.2)		42.6 (34.6)
Median (IQR)	52.5 (5.0 - 100.0)		30.0 (16.0 - 70.0)
Min ; Max	5 ; 100		2 ; 111
Duration from onset of sPPH to administration of first Fibrinogen (minutes)			
N	1	0	7
Mean (SD)	230.0 (NE)		45.4 (25.4)
Median (IQR)	230.0 (230.0 - 230.0)		42.0 (27.0 - 53.0)
Min ; Max	230 ; 230		16 ; 95
Duration from onset of sPPH to first NovoSeven® (minutes)			
N	2	0	15
Mean (SD)	65.0 (21.2)		116.9 (156.8)
Median (IQR)	65.0 (50.0 - 80.0)		71.0 (28.0 - 121.0)
Min ; Max	50 ; 80		3 ; 635
Duration from onset of sPPH to stop of PPH (minutes)			
N	2	0	15
Mean (SD)	1514.0 (1851.2)		205.5 (188.6)
Median (IQR)	1514.0 (205.0 - 2823.0)		155.0 (88.0 - 232.0)
Min ; Max	205 ; 2823		57 ; 675

PS: Propensity score, sPPH: Severe postpartum haemorrhage, TXA: Tranexamic acid, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), PPH: Postpartum haemorrhage.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure:

First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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Control of bleeding - by timing of first NovoSeven® dose from invasive procedure - PS analysis set

After first invasive procedure Missing

Number of patients	1	0
Duration from onset of sPPH to administration of first TXA (minutes)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Duration from onset of sPPH to administration of first Fibrinogen (minutes)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Duration from onset of sPPH to first NovoSeven® (minutes)		
N	1	0
Mean (SD)	584.0 (NE)	
Median (IQR)	584.0 (584.0 - 584.0)	
Min ; Max	584 ; 584	
Duration from onset of sPPH to stop of PPH (minutes)		
N	1	0
Mean (SD)	896.0 (NE)	
Median (IQR)	896.0 (896.0 - 896.0)	
Min ; Max	896 ; 896	

PS: Propensity score, sPPH: Severe postpartum haemorrhage, TXA: Tranexamic acid, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), PPH: Postpartum haemorrhage.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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14.2.56 Control of bleeding - by first NovoSeven® administration time from onset of sPPH - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Number of patients	4	14
Duration from onset of sPPH to administration of first TXA (minutes)		
N	2	10
Mean (SD)	28.0 (4.2)	47.5 (40.5)
Median (IQR)	28.0 (25.0 - 31.0)	42.5 (10.0 - 76.0)
Min ; Max	25 ; 31	2 ; 111
Duration from onset of sPPH to administration of first Fibrinogen (minutes)		
N	3	5
Mean (SD)	26.0 (9.5)	94.0 (78.8)
Median (IQR)	27.0 (16.0 - 35.0)	53.0 (50.0 - 95.0)
Min ; Max	16 ; 35	42 ; 230
Duration from onset of sPPH to first NovoSeven® (minutes)		
N	4	14
Mean (SD)	15.5 (10.2)	171.8 (193.0)
Median (IQR)	15.5 (9.0 - 22.0)	94.5 (62.0 - 135.0)
Min ; Max	3 ; 28	50 ; 635
Duration from onset of sPPH to stop of PPH (minutes)		
N	4	14
Mean (SD)	79.5 (18.0)	477.7 (719.2)
Median (IQR)	80.0 (68.0 - 91.0)	193.0 (155.0 - 625.0)
Min ; Max	57 ; 101	88 ; 2823

PS: Propensity score, sPPH: Severe postpartum haemorrhage, TXA: Tranexamic acid, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), PPH: Postpartum haemorrhage.

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14.2.57 Control of bleeding - by first dose of NovoSeven® (µg/kg) - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Number of patients	2	16	0
Duration from onset of sPPH to administration of first TXA (minutes)			
N	0	12	0
Mean (SD)		44.3 (37.5)	
Median (IQR)		30.0 (13.0 - 73.0)	
Min ; Max		2 ; 111	
Duration from onset of sPPH to administration of first Fibrinogen (minutes)			
N	1	7	0
Mean (SD)	27.0 (NE)	74.4 (72.7)	
Median (IQR)	27.0 (27.0 - 27.0)	50.0 (35.0 - 95.0)	
Min ; Max	27 ; 27	16 ; 230	
Duration from onset of sPPH to first NovoSeven® (minutes)			
N	2	16	0
Mean (SD)	293.5 (410.8)	117.5 (149.9)	
Median (IQR)	293.5 (3.0 - 584.0)	73.0 (53.0 - 115.0)	
Min ; Max	3 ; 584	15 ; 635	
Duration from onset of sPPH to stop of PPH (minutes)			
N	2	16	0
Mean (SD)	487.5 (577.7)	376.9 (676.4)	
Median (IQR)	487.5 (79.0 - 896.0)	167.5 (104.0 - 233.5)	
Min ; Max	79 ; 896	57 ; 2823	

PS: Propensity score, sPPH: Severe postpartum haemorrhage, TXA: Tranexamic acid, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), PPH: Postpartum haemorrhage.

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14.2.58 Control of bleeding - by gestational age for patients exposed to NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	2	11	5	0
Duration from onset of sPPH to administration of first TXA (minutes)				
N	2	7	3	0
Mean (SD)	62.5 (53.0)	45.9 (37.8)	28.3 (36.2)	
Median (IQR)	62.5 (25.0 - 100.0)	31.0 (16.0 - 76.0)	10.0 (5.0 - 70.0)	
Min ; Max	25 ; 100	2 ; 111	5 ; 70	
Duration from onset of sPPH to administration of first Fibrinogen (minutes)				
N	1	4	3	0
Mean (SD)	35.0 (NE)	34.5 (16.3)	125.0 (93.7)	
Median (IQR)	35.0 (35.0 - 35.0)	34.5 (21.5 - 47.5)	95.0 (50.0 - 230.0)	
Min ; Max	35 ; 35	16 ; 53	50 ; 230	
Duration from onset of sPPH to first NovoSeven® (minutes)				
N	2	11	5	0
Mean (SD)	47.5 (46.0)	113.2 (161.7)	225.4 (242.8)	
Median (IQR)	47.5 (15.0 - 80.0)	62.0 (28.0 - 121.0)	109.0 (75.0 - 258.0)	
Min ; Max	15 ; 80	3 ; 584	50 ; 635	
Duration from onset of sPPH to stop of PPH (minutes)				
N	2	11	5	0
Mean (SD)	131.0 (104.7)	207.7 (235.1)	891.8 (1106.3)	
Median (IQR)	131.0 (57.0 - 205.0)	131.0 (88.0 - 232.0)	625.0 (181.0 - 675.0)	
Min ; Max	57 ; 205	79 ; 896	155 ; 2823	

PS: Propensity score, sPPH: Severe postpartum haemorrhage, TXA: Tranexamic acid, N: Number of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), PPH: Postpartum haemorrhage.

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14.2.59 Control of bleeding - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	1	26	16	0
Number of weighted patients, N	0.3	8.1	9.7	0
Duration from onset of sPPH to administration of first TXA (minutes)				
N	0.3	5.7	6.6	0
Mean (SD)	24.0 (NE)	111.9 (196.5)	422.1 (422.7)	
Median (IQR)	24.0 (24.0 - 24.0)	27.0 (5.0 - 56.0)	165.0 (120.0 - 692.0)	
Min ; Max	24 ; 24	4 ; 1685	5 ; 1549	
Duration from onset of sPPH to administration of first Fibrinogen (minutes)				
N	0.3	2.1	3.8	0
Mean (SD)	109.0 (NE)	110.7 (56.8)	96.8 (38.5)	
Median (IQR)	109.0 (109.0 - 109.0)	66.0 (44.0 - 137.0)	95.0 (70.0 - 156.0)	
Min ; Max	109 ; 109	15 ; 368	10 ; 182	
Duration from onset of sPPH to first NovoSeven® (minutes)				
N	0	0	0	0
Mean (SD)				
Median (IQR)				
Min ; Max				
Duration from onset of sPPH to stop of PPH (minutes)				
N	0.3	8.1	9.7	0
Mean (SD)	246.0 (NE)	603.3 (551.6)	515.6 (349.1)	
Median (IQR)	246.0 (246.0 - 246.0)	142.0 (111.0 - 279.0)	327.0 (217.0 - 675.0)	
Min ; Max	246 ; 246	40 ; 3910	124 ; 1619	

PS: Propensity score, sPPH: Severe postpartum haemorrhage, TXA: Tranexamic acid, N: Number of (weighted) patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), PPH: Postpartum haemorrhage.

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18AUG2021:14:42:18 - tsumcbled.sas/tsumcbledgagcctrlpsas.txt

14.2.60 Secondary endpoint - incidence of hysterectomy - statistical analysis - PS analysis set

	PSAS	N	n	Estimate	95% CI	p-value
Hysterectomy						
Observed data						
NovoSeven®	18	18	2	11.1		
Matched controls	43	42	8	19.0		
Weighted data						
NovoSeven®	18	18	2	11.1	[-5.0 ; 27.2]	
Matched controls	18.0	17.8	3.1	17.4	[5.4 ; 29.3]	
Adjusted Odds ratio						
NovoSeven®/Matched controls				0.52	[0.05 ; 3.03]	0.6815

PS: Propensity score, PSAS: Propensity score analysis set, N: Number of (weighted) Patients used in analysis, n: Number of (weighted) patients having hysterectomy, CI: confidence interval, NE: Not estimable. Observed data is the raw proportion of events in each group. The weighted data is the proportion with 95% Wald's confidence interval in each group where the matched controls are weighted according to number of controls selected in the matching process to adjust for difference in number of controls across NovoSeven® exposed women. Odds ratio for invasive procedures were compared between NovoSeven® and matched control based on a exact conditional logistic regression model with a 95% exact confidence interval based on the propensity score matching, along with p-value. Patient with hysterectomy in the conjoint period are excluded from the PS analysis set (0 patients with NovoSeven® and 1 matched controls).

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14.2.61 NovoSeven® administration from onset of sPPH - full analysis set

	PS analysis set	Full analysis set
	NovoSeven®	NovoSeven®
1.0 Number of patients	18	52
Time from onset of sPPH to first dose of NovoSeven® (minutes)		
N	18	52
Mean (SD)	137.1 (181.6)	228.2 (266.6)
Median (IQR)	73.0 (50.0 - 121.0)	127.5 (71.0 - 290.5)
Min ; Max	3 ; 635	3 ; 1569
Time from onset of sPPH to first dose of NovoSeven® for women receiving only one dose (minutes)		
N	17	46
Mean (SD)	141.5 (186.2)	234.7 (280.7)
Median (IQR)	75.0 (50.0 - 121.0)	131.5 (71.0 - 297.0)
Min ; Max	3 ; 635	3 ; 1569
Time from first dose to second dose of NovoSeven® (minutes)		
N	1	6
Mean (SD)	40.0 (NE)	216.3 (431.7)
Median (IQR)	40.0 (40.0 - 40.0)	40.0 (18.0 - 100.0)
Min ; Max	40 ; 40	5 ; 1095
Time from second dose to third dose of NovoSeven® (minutes)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PS: Propensity score, sPPH: Severe postpartum haemorrhage, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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14.2.62 NovoSeven® administration from onset of sPPH - by concomitant use - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	7	7	1	3
Time from onset of sPPH to first dose of NovoSeven® (minutes)				
N	7	7	1	3
Mean (SD)	66.3 (87.8)	77.1 (31.2)	635.0 (NE)	276.0 (267.1)
Median (IQR)	50.0 (15.0 - 62.0)	75.0 (56.0 - 109.0)	635.0 (635.0 - 635.0)	135.0 (109.0 - 584.0)
Min ; Max	3 ; 258	28 ; 121	635 ; 635	109 ; 584
Time from onset of sPPH to first dose of NovoSeven® for women receiving only one dose (minutes)				
N	6	7	1	3
Mean (SD)	67.0 (96.1)	77.1 (31.2)	635.0 (NE)	276.0 (267.1)
Median (IQR)	33.0 (15.0 - 60.0)	75.0 (56.0 - 109.0)	635.0 (635.0 - 635.0)	135.0 (109.0 - 584.0)
Min ; Max	3 ; 258	28 ; 121	635 ; 635	109 ; 584
Time from first dose to second dose of NovoSeven® (minutes)				
N	1	0	0	0
Mean (SD)	40.0 (NE)			
Median (IQR)	40.0 (40.0 - 40.0)			
Min ; Max	40 ; 40			

PS: Propensity score, sPPH: Severe postpartum haemorrhage, TXA: Tranexamic acid, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.
Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(=)/after(>) time0.

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14.2.63 NovoSeven® administration from onset of sPPH - by cause of PPH - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony	Trauma	Other
Number of patients	4	1	0	13	0	0
Time from onset of sPPH to first dose of NovoSeven® (minutes)						
N	4	1	0	13	0	0
Mean (SD)	76.0 (31.2)	3.0 (NE)		166.2 (207.0)		
Median (IQR)	66.5 (56.0 - 96.0)	3.0 (3.0 - 3.0)		80.0 (56.0 - 135.0)		
Min ; Max	50 ; 121	3 ; 3		15 ; 635		
Time from onset of sPPH to first dose of NovoSeven® for women receiving only one dose (minutes)						
N	3	1	0	13	0	0
Mean (SD)	80.7 (36.5)	3.0 (NE)		166.2 (207.0)		
Median (IQR)	71.0 (50.0 - 121.0)	3.0 (3.0 - 3.0)		80.0 (56.0 - 135.0)		
Min ; Max	50 ; 121	3 ; 3		15 ; 635		
Time from first dose to second dose of NovoSeven® (minutes)						
N	1	0	0	0	0	0
Mean (SD)	40.0 (NE)					
Median (IQR)	40.0 (40.0 - 40.0)					
Min ; Max	40 ; 40					

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), sPPH: Severe postpartum haemorrhage, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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14.2.64 NovoSeven® administration from onset of sPPH - by timing of first NovoSeven® dose from invasive procedure - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
1.0 Number of patients	2	0	15
Time from onset of sPPH to first dose of NovoSeven® (minutes)			
N	2	0	15
Mean (SD)	65.0 (21.2)		116.9 (156.8)
Median (IQR)	65.0 (50.0 - 80.0)		71.0 (28.0 - 121.0)
Min ; Max	50 ; 80		3 ; 635
Time from onset of sPPH to first dose of NovoSeven® for women receiving only one dose (minutes)			
N	2	0	14
Mean (SD)	65.0 (21.2)		120.8 (161.9)
Median (IQR)	65.0 (50.0 - 80.0)		73.0 (28.0 - 121.0)
Min ; Max	50 ; 80		3 ; 635
Time from first dose to second dose of NovoSeven® (minutes)			
N	0	0	1
Mean (SD)			40.0 (NE)
Median (IQR)			40.0 (40.0 - 40.0)
Min ; Max			40 ; 40

PS: Propensity score, sPPH: Severe postpartum haemorrhage, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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NovoSeven® administration from onset of sPPH - by timing of first NovoSeven® dose from invasive procedure - PS analysis set

	After first invasive procedure	Missing
1.0 Number of patients	1	0
Time from onset of sPPH to first dose of NovoSeven® (minutes)		
N	1	0
Mean (SD)	584.0 (NE)	
Median (IQR)	584.0 (584.0 - 584.0)	
Min ; Max	584 ; 584	
Time from onset of sPPH to first dose of NovoSeven® for women receiving only one dose (minutes)		
N	1	0
Mean (SD)	584.0 (NE)	
Median (IQR)	584.0 (584.0 - 584.0)	
Min ; Max	584 ; 584	
Time from first dose to second dose of NovoSeven® (minutes)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PS: Propensity score, sPPH: Severe postpartum haemorrhage, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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14.2.65 NovoSeven® administration from onset of sPPH - by first NovoSeven® administration time from onset of sPPH - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH

Number of patients	4	14
Time from onset of sPPH to first dose of NovoSeven® (minutes)		
N	4	14
Mean (SD)	15.5 (10.2)	171.8 (193.0)
Median (IQR)	15.5 (9.0 - 22.0)	94.5 (62.0 - 135.0)
Min ; Max	3 ; 28	50 ; 635
Time from onset of sPPH to first dose of NovoSeven® for women receiving only one dose (minutes)		
N	4	13
Mean (SD)	15.5 (10.2)	180.2 (198.2)
Median (IQR)	15.5 (9.0 - 22.0)	109.0 (71.0 - 135.0)
Min ; Max	3 ; 28	50 ; 635
Time from first dose to second dose of NovoSeven® (minutes)		
N	0	1
Mean (SD)		40.0 (NE)
Median (IQR)		40.0 (40.0 - 40.0)
Min ; Max		40 ; 40

PS: Propensity score, sPPH: Severe postpartum haemorrhage, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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14.2.66 NovoSeven® administration from onset of sPPH - by first dose of NovoSeven® (µg/kg) - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Number of patients	2	16	0
Time from onset of sPPH to first dose of NovoSeven® (minutes)			
N	2	16	0
Mean (SD)	293.5 (410.8)	117.5 (149.9)	
Median (IQR)	293.5 (3.0 - 584.0)	73.0 (53.0 - 115.0)	
Min ; Max	3 ; 584	15 ; 635	
Time from onset of sPPH to first dose of NovoSeven® for women receiving only one dose (minutes)			
N	2	15	0
Mean (SD)	293.5 (410.8)	121.2 (154.4)	
Median (IQR)	293.5 (3.0 - 584.0)	75.0 (50.0 - 121.0)	
Min ; Max	3 ; 584	15 ; 635	
Time from first dose to second dose of NovoSeven® (minutes)			
N	0	1	0
Mean (SD)		40.0 (NE)	
Median (IQR)		40.0 (40.0 - 40.0)	
Min ; Max		40 ; 40	

PS: Propensity score, sPPH: Severe postpartum haemorrhage, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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14.2.67 NovoSeven® administration from onset of sPPH - by gestational age - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	2	11	5	0
Time from onset of sPPH to first dose of NovoSeven® (minutes)				
N	2	11	5	0
Mean (SD)	47.5 (46.0)	113.2 (161.7)	225.4 (242.8)	
Median (IQR)	47.5 (15.0 - 80.0)	62.0 (28.0 - 121.0)	109.0 (75.0 - 258.0)	
Min ; Max	15 ; 80	3 ; 584	50 ; 635	
Time from onset of sPPH to first dose of NovoSeven® for women receiving only one dose (minutes)				
N	2	10	5	0
Mean (SD)	47.5 (46.0)	118.3 (169.5)	225.4 (242.8)	
Median (IQR)	47.5 (15.0 - 80.0)	65.5 (28.0 - 121.0)	109.0 (75.0 - 258.0)	
Min ; Max	15 ; 80	3 ; 584	50 ; 635	
Time from first dose to second dose of NovoSeven® (minutes)				
N	0	1	0	0
Mean (SD)		40.0 (NE)		
Median (IQR)		40.0 (40.0 - 40.0)		
Min ; Max		40 ; 40		

PS: Propensity score, sPPH: Severe postpartum haemorrhage, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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14.2.68 Overall clinical outcomes - full analysis set

	PS Analysis set		Full analysis set		
	NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total
Number of patients	18	43	52	113	165
Invasive procedure , N (%)					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
Any invasive procedure	16 (88.9)	14.1 (78.2)	40 (76.9)	32 (28.3)	72 (43.6)
Hysterectomy	2 (11.1)	3.6 (19.9)	11 (21.2)	11 (9.7)	22 (13.3)
Radiological arterial embolisation	1 (5.6)	2.0 (11.1)	7 (13.5)	5 (4.4)	12 (7.3)
Uterine compression sutures	14 (77.8)	10.3 (56.9)	30 (57.7)	20 (17.7)	50 (30.3)
Uterine or iliac artery ligation	1 (5.6)	2.0 (11.1)	4 (7.7)	2 (1.8)	6 (3.6)
Other*	0	0	0	0	0
No	2 (11.1)	3.9 (21.8)	12 (23.1)	81 (71.7)	93 (56.4)
Missing	0	0	0	3 (2.7)	3 (1.8)
Intrauterine balloon, N (%)					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
Yes	0	2.8 (15.3)	6 (11.5)	20 (17.7)	26 (15.8)
No	18 (100.0)	15.3 (84.7)	46 (88.5)	93 (82.3)	139 (84.2)
Missing	0	0	0	0	0
Other tamponade, N (%)					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
Yes	2 (11.1)	4.3 (24.1)	12 (23.1)	10 (8.8)	22 (13.3)
No	16 (88.9)	13.7 (75.9)	40 (76.9)	103 (91.2)	143 (86.7)
Missing	0	0	0	0	0

PS: Propensity score, N: Number of (weighted) Patients, %: Percentage of (weighted) patients, Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

*Death is imputed as other invasive procedure.

Invasive procedure with missing time will be counted in Missing category.

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14.2.69 Clinical outcomes - full analysis set

PS analysis set			Full analysis set		
	NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total
1.0 Number of patients	18	43	52	113	165
Number of weighted patients, N		18.0			
Hysterectomy in conjoint period, N (%)					
Yes	0	0	2 (3.8)		
No	18 (100.0)	18.0 (100.0)	50 (96.2)		
Missing	0	0	0		
Other invasive procedure(s) in conjoint period, N (%)					
Yes	4 (22.2)	2.5 (13.9)	7 (13.5)		
No	14 (77.8)	15.5 (86.1)	45 (86.5)		
Missing	0	0	0		
Hysterectomy and other invasive procedure(s) in conjoint period, N (%)					
Yes	0	0.3 (1.4)	0		
No	18 (100.0)	17.8 (98.6)	52 (100.0)		
Missing	0	0	0		
Any invasive procedure(s) in conjoint period, N (%)					
Yes	4 (22.2)	2.8 (15.3)	9 (17.3)		
No	14 (77.8)	15.3 (84.7)	43 (82.7)		
Missing	0	0	0		

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - full analysis set

		PS analysis set		Full analysis set		
		NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total
1.0	Laparotomy in conjoint period, N (%)					
	Yes	2 (11.1)	0.8 (4.6)	4 (7.7)		
	No	16 (88.9)	17.2 (95.4)	48 (92.3)		
	Missing	0	0	0		
	Intrauterine balloon in conjoint period, N (%)					
	Yes	0	0.3 (1.4)	0		
	No	18 (100.0)	17.8 (98.6)	52 (100.0)		
	Missing	0	0	0		
	Other tamponade in conjoint period, N (%)					
	Yes	0	1.0 (5.6)	1 (1.9)		
	No	18 (100.0)	17.0 (94.4)	51 (98.1)		
	Missing	0	0	0		
	Removal of placenta in conjoint period, N (%)					
	Yes	0	0	1 (1.9)		
	No	18 (100.0)	18.0 (100.0)	51 (98.1)		
	Missing	0	0	0		

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - full analysis set

	PS analysis set		Full analysis set		
	NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total
Hysterectomy after conjoint period, N (%)					
Yes	2 (11.1)	1.8 (10.2)	5 (9.6)		
No	16 (88.9)	16.2 (89.8)	47 (90.4)		
Missing	0	0	0		
Other invasive procedure(s) after conjoint period, N (%)					
Yes	1 (5.6)	2.5 (13.9)	6 (11.5)		
No	17 (94.4)	15.5 (86.1)	46 (88.5)		
Missing	0	0	0		
Hysterectomy and other invasive procedure(s) after conjoint period, N (%)					
Yes	0	1.3 (6.9)	0		
No	18 (100.0)	16.8 (93.1)	52 (100.0)		
Missing	0	0	0		
Any invasive procedure(s) after conjoint period, N (%)					
Yes	3 (16.7)	5.6 (31.0)	11 (21.2)		
No	15 (83.3)	12.4 (69.0)	41 (78.8)		
Missing	0	0	0		

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - full analysis set

		PS analysis set		Full analysis set		
		NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total
1.0	Laparotomy after conjoint period, N (%)					
	Yes	1 (5.6)	3.3 (18.1)	2 (3.8)		
	No	17 (94.4)	14.8 (81.9)	50 (96.2)		
	Missing	0	0	0		
	Intrauterine balloon after conjoint period, N (%)					
	Yes	0	0	1 (1.9)		
	No	18 (100.0)	18.0 (100.0)	51 (98.1)		
	Missing	0	0	0		
	Other tamponade after conjoint period, N (%)					
	Yes	1 (5.6)	0	2 (3.8)		
	No	17 (94.4)	18.0 (100.0)	50 (96.2)		
	Missing	0	0	0		
	Removal of placenta after conjoint period, N (%)					
	Yes	0	0	0		
	No	18 (100.0)	18.0 (100.0)	52 (100.0)		
	Missing	0	0	0		

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.2.70 Clinical outcomes - by concomitant use before time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	4	7	2	5
Hysterectomy in conjoint period, N (%)				
Yes	0	0	0	0
No	4 (100.0)	7 (100.0)	2 (100.0)	5 (100.0)
Missing	0	0	0	0
Other invasive procedure(s) in conjoint period, N (%)				
Yes	1 (25.0)	0	1 (50.0)	2 (40.0)
No	3 (75.0)	7 (100.0)	1 (50.0)	3 (60.0)
Missing	0	0	0	0
Hysterectomy and other invasive procedure(s) in conjoint period, N (%)				
Yes	0	0	0	0
No	4 (100.0)	7 (100.0)	2 (100.0)	5 (100.0)
Missing	0	0	0	0
Any invasive procedure(s) in conjoint period, N (%)				
Yes	1 (25.0)	0	1 (50.0)	2 (40.0)
No	3 (75.0)	7 (100.0)	1 (50.0)	3 (60.0)
Missing	0	0	0	0

PS: Propensity score, TXA: Tranexamic acid, N: Number of patients, %: Percentage of patients.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by concomitant use before time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Laparotomy in conjoint period, N (%)				
Yes	1 (25.0)	0	0	1 (20.0)
No	3 (75.0)	7 (100.0)	2 (100.0)	4 (80.0)
Missing	0	0	0	0
Intrauterine balloon in conjoint period, N (%)				
Yes	0	0	0	0
No	4 (100.0)	7 (100.0)	2 (100.0)	5 (100.0)
Missing	0	0	0	0
Other tamponade in conjoint period, N (%)				
Yes	0	0	0	0
No	4 (100.0)	7 (100.0)	2 (100.0)	5 (100.0)
Missing	0	0	0	0
Removal of placenta in conjoint period, N (%)				
Yes	0	0	0	0
No	4 (100.0)	7 (100.0)	2 (100.0)	5 (100.0)
Missing	0	0	0	0

PS: Propensity score, TXA: Tranexamic acid, N: Number of patients, %: Percentage of patients.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by concomitant use before time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Hysterectomy after conjoint period, N (%)				
Yes	0	1 (14.3)	0	1 (20.0)
No	4 (100.0)	6 (85.7)	2 (100.0)	4 (80.0)
Missing	0	0	0	0
Other invasive procedure(s) after conjoint period, N (%)				
Yes	1 (25.0)	0	0	0
No	3 (75.0)	7 (100.0)	2 (100.0)	5 (100.0)
Missing	0	0	0	0
Hysterectomy and other invasive procedure(s) after conjoint period, N (%)				
Yes	0	0	0	0
No	4 (100.0)	7 (100.0)	2 (100.0)	5 (100.0)
Missing	0	0	0	0
Any invasive procedure(s) after conjoint period, N (%)				
Yes	1 (25.0)	1 (14.3)	0	1 (20.0)
No	3 (75.0)	6 (85.7)	2 (100.0)	4 (80.0)
Missing	0	0	0	0

PS: Propensity score, TXA: Tranexamic acid, N: Number of patients, %: Percentage of patients.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by concomitant use before time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Laparotomy after conjoint period, N (%)				
Yes	0	0	0	1 (20.0)
No	4 (100.0)	7 (100.0)	2 (100.0)	4 (80.0)
Missing	0	0	0	0
Intrauterine balloon after conjoint period, N (%)				
Yes	0	0	0	0
No	4 (100.0)	7 (100.0)	2 (100.0)	5 (100.0)
Missing	0	0	0	0
Other tamponade after conjoint period, N (%)				
Yes	0	1 (14.3)	0	0
No	4 (100.0)	6 (85.7)	2 (100.0)	5 (100.0)
Missing	0	0	0	0
Removal of placenta after conjoint period, N (%)				
Yes	0	0	0	0
No	4 (100.0)	7 (100.0)	2 (100.0)	5 (100.0)
Missing	0	0	0	0

PS: Propensity score, TXA: Tranexamic acid, N: Number of patients, %: Percentage of patients.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.2.71 Clinical outcomes - by concomitant use before time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	4	17	1	21
Number of weighted patients, N	1.6	6.7	1.0	8.8
Hysterectomy in conjoint period, N (%)				
Yes	0	0	0	0
No	1.6 (100.0)	6.7 (100.0)	1.0 (100.0)	8.8 (100.0)
Missing	0	0	0	0
Other invasive procedure(s) in conjoint period, N (%)				
Yes	0.3 (15.8)	0.5 (7.5)	0	1.8 (20.0)
No	1.3 (84.2)	6.2 (92.5)	1.0 (100.0)	7.0 (80.0)
Missing	0	0	0	0
Hysterectomy and other invasive procedure(s) in conjoint period, N (%)				
Yes	0	0	0	0.3 (2.9)
No	1.6 (100.0)	6.7 (100.0)	1.0 (100.0)	8.5 (97.1)
Missing	0	0	0	0
Any invasive procedure(s) in conjoint period, N (%)				
Yes	0.3 (15.8)	0.5 (7.5)	0	2.0 (22.9)
No	1.3 (84.2)	6.2 (92.5)	1.0 (100.0)	6.8 (77.1)
Missing	0	0	0	0

PS: Propensity score, TXA: Tranexamic acid, N: Number of (weighted) patients, %: Percentage of patients.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(=) time0.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by concomitant use before time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Laparotomy in conjoint period, N (%)				
Yes	0	0.5 (7.5)	0	0.3 (3.8)
No	1.6 (100.0)	6.2 (92.5)	1.0 (100.0)	8.4 (96.2)
Missing	0	0	0	0
Intrauterine balloon in conjoint period, N (%)				
Yes	0	0.3 (3.8)	0	0
No	1.6 (100.0)	6.4 (96.3)	1.0 (100.0)	8.8 (100.0)
Missing	0	0	0	0
Other tamponade in conjoint period, N (%)				
Yes	0	0	1.0 (100.0)	0
No	1.6 (100.0)	6.7 (100.0)	0	8.8 (100.0)
Missing	0	0	0	0
Removal of placenta in conjoint period, N (%)				
Yes	0	0	0	0
No	1.6 (100.0)	6.7 (100.0)	1.0 (100.0)	8.8 (100.0)
Missing	0	0	0	0

PS: Propensity score, TXA: Tranexamic acid, N: Number of (weighted) patients, %: Percentage of patients.
Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(≤) time0.
Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by concomitant use before time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Hysterectomy after conjoint period, N (%)				
Yes	0	0.5 (7.5)	0	1.3 (15.2)
No	1.6 (100.0)	6.2 (92.5)	1.0 (100.0)	7.4 (84.8)
Missing	0	0	0	0
Other invasive procedure(s) after conjoint period, N (%)				
Yes	0.5 (31.6)	1.0 (15.0)	1.0 (100.0)	0
No	1.1 (68.4)	5.7 (85.0)	0	8.8 (100.0)
Missing	0	0	0	0
Hysterectomy and other invasive procedure(s) after conjoint period, N (%)				
Yes	0	0.3 (3.8)	0	1.0 (11.4)
No	1.6 (100.0)	6.4 (96.3)	1.0 (100.0)	7.8 (88.6)
Missing	0	0	0	0
Any invasive procedure(s) after conjoint period, N (%)				
Yes	0.5 (31.6)	1.8 (26.3)	1.0 (100.0)	2.3 (26.7)
No	1.1 (68.4)	4.9 (73.8)	0	6.4 (73.3)
Missing	0	0	0	0

PS: Propensity score, TXA: Tranexamic acid, N: Number of (weighted) patients, %: Percentage of patients.
 Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.
 Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by concomitant use before time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Laparotomy after conjoint period, N (%)				
Yes	0	0.8 (11.3)	1.0 (100.0)	1.5 (17.1)
No	1.6 (100.0)	5.9 (88.7)	0	7.3 (82.9)
Missing	0	0	0	0
Intrauterine balloon after conjoint period, N (%)				
Yes	0	0	0	0
No	1.6 (100.0)	6.7 (100.0)	1.0 (100.0)	8.8 (100.0)
Missing	0	0	0	0
Other tamponade after conjoint period, N (%)				
Yes	0	0	0	0
No	1.6 (100.0)	6.7 (100.0)	1.0 (100.0)	8.8 (100.0)
Missing	0	0	0	0
Removal of placenta after conjoint period, N (%)				
Yes	0	0	0	0
No	1.6 (100.0)	6.7 (100.0)	1.0 (100.0)	8.8 (100.0)
Missing	0	0	0	0

PS: Propensity score, TXA: Tranexamic acid, N: Number of (weighted) patients, %: Percentage of patients.
 Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.
 Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.2.72 Clinical outcomes - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony	Trauma	Other
Number of patients	4	1	0	13	0	0
Hysterectomy in conjoint period, N (%)						
Yes	0	0	0	0	0	0
No	4 (100.0)	1 (100.0)	0	13 (100.0)	0	0
Missing	0	0	0	0	0	0
Other invasive procedure(s) in conjoint period, N (%)						
Yes	0	1 (100.0)	0	3 (23.1)	0	0
No	4 (100.0)	0	0	10 (76.9)	0	0
Missing	0	0	0	0	0	0
Hysterectomy and other invasive procedure(s) in conjoint period, N (%)						
Yes	0	0	0	0	0	0
No	4 (100.0)	1 (100.0)	0	13 (100.0)	0	0
Missing	0	0	0	0	0	0
Any invasive procedure(s) in conjoint period, N (%)						
Yes	0	1 (100.0)	0	3 (23.1)	0	0
No	4 (100.0)	0	0	10 (76.9)	0	0
Missing	0	0	0	0	0	0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony	Trauma	Other
Laparotomy in conjoint period, N (%)						
Yes	0	1 (100.0)	0	1 (7.7)	0	0
No	4 (100.0)	0	0	12 (92.3)	0	0
Missing	0	0	0	0	0	0
Intrauterine balloon in conjoint period, N (%)						
Yes	0	0	0	0	0	0
No	4 (100.0)	1 (100.0)	0	13 (100.0)	0	0
Missing	0	0	0	0	0	0
Other tamponade in conjoint period, N (%)						
Yes	0	0	0	0	0	0
No	4 (100.0)	1 (100.0)	0	13 (100.0)	0	0
Missing	0	0	0	0	0	0
Removal of placenta in conjoint period, N (%)						
Yes	0	0	0	0	0	0
No	4 (100.0)	1 (100.0)	0	13 (100.0)	0	0
Missing	0	0	0	0	0	0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

1.0

	AIP	Placental abruption	Placental retention	Uterine atony	Trauma	Other
Hysterectomy after conjoint period, N (%)						
Yes	1 (25.0)	0	0	1 (7.7)	0	0
No	3 (75.0)	1 (100.0)	0	12 (92.3)	0	0
Missing	0	0	0	0	0	0
Other invasive procedure(s) after conjoint period, N (%)						
Yes	0	0	0	1 (7.7)	0	0
No	4 (100.0)	1 (100.0)	0	12 (92.3)	0	0
Missing	0	0	0	0	0	0
Hysterectomy and other invasive procedure(s) after conjoint period, N (%)						
Yes	0	0	0	0	0	0
No	4 (100.0)	1 (100.0)	0	13 (100.0)	0	0
Missing	0	0	0	0	0	0
Any invasive procedure(s) after conjoint period, N (%)						
Yes	1 (25.0)	0	0	2 (15.4)	0	0
No	3 (75.0)	1 (100.0)	0	11 (84.6)	0	0
Missing	0	0	0	0	0	0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony	Trauma	Other
Laparotomy after conjoint period, N (%)						
Yes	0	0	0	1 (7.7)	0	0
No	4 (100.0)	1 (100.0)	0	12 (92.3)	0	0
Missing	0	0	0	0	0	0
Intrauterine balloon after conjoint period, N (%)						
Yes	0	0	0	0	0	0
No	4 (100.0)	1 (100.0)	0	13 (100.0)	0	0
Missing	0	0	0	0	0	0
Other tamponade after conjoint period, N (%)						
Yes	1 (25.0)	0	0	0	0	0
No	3 (75.0)	1 (100.0)	0	13 (100.0)	0	0
Missing	0	0	0	0	0	0
Removal of placenta after conjoint period, N (%)						
Yes	0	0	0	0	0	0
No	4 (100.0)	1 (100.0)	0	13 (100.0)	0	0
Missing	0	0	0	0	0	0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.2.73 Clinical outcomes - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony	Trauma	Other
Number of patients	14	3	0	23	2	1
Number of weighted patients, N	5.0	2.3	0	8.4	1.3	1.0
Hysterectomy in conjoint period, N (%)						
Yes	0	0	0	0	0	0
No	5.0 (100.0)	2.3 (100.0)	0	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0
Other invasive procedure(s) in conjoint period, N (%)						
Yes	0.8 (15.0)	0	0	1.8 (20.8)	0	0
No	4.3 (85.0)	2.3 (100.0)	0	6.7 (79.2)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0
Hysterectomy and other invasive procedure(s) in conjoint period, N (%)						
Yes	0.3 (5.0)	0	0	0	0	0
No	4.8 (95.0)	2.3 (100.0)	0	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0
Any invasive procedure(s) in conjoint period, N (%)						
Yes	1.0 (20.0)	0	0	1.8 (20.8)	0	0
No	4.0 (80.0)	2.3 (100.0)	0	6.7 (79.2)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by cause of PPH for matched controls - PS analysis set

1.0

	AIP	Placental abruption	Placental retention	Uterine atony	Trauma	Other
Laparotomy in conjoint period, N (%)						
Yes	0.5 (10.0)	0	0	0.3 (4.0)	0	0
No	4.5 (90.0)	2.3 (100.0)	0	8.1 (96.0)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0
Intrauterine balloon in conjoint period, N (%)						
Yes	0.3 (5.0)	0	0	0	0	0
No	4.8 (95.0)	2.3 (100.0)	0	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0
Other tamponade in conjoint period, N (%)						
Yes	0	0	0	1.0 (11.9)	0	0
No	5.0 (100.0)	2.3 (100.0)	0	7.4 (88.1)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0
Removal of placenta in conjoint period, N (%)						
Yes	0	0	0	0	0	0
No	5.0 (100.0)	2.3 (100.0)	0	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony	Trauma	Other
Hysterectomy after conjoint period, N (%)						
Yes	0.8 (15.0)	0	0	1.1 (12.9)	0	0
No	4.3 (85.0)	2.3 (100.0)	0	7.3 (87.1)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0
Other invasive procedure(s) after conjoint period, N (%)						
Yes	1.0 (20.0)	0	0	1.5 (17.8)	0	0
No	4.0 (80.0)	2.3 (100.0)	0	6.9 (82.2)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0
Hysterectomy and other invasive procedure(s) after conjoint period, N (%)						
Yes	0	0	0	1.3 (14.9)	0	0
No	5.0 (100.0)	2.3 (100.0)	0	7.2 (85.1)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0
Any invasive procedure(s) after conjoint period, N (%)						
Yes	1.8 (35.0)	0	0	3.8 (45.5)	0	0
No	3.3 (65.0)	2.3 (100.0)	0	4.6 (54.5)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by cause of PPH for matched controls - PS analysis set

1.0

	AIP	Placental abruption	Placental retention	Uterine atony	Trauma	Other
Laparotomy after conjoint period, N (%)						
Yes	0	0	0	2.3 (26.7)	0	1.0 (100.0)
No	5.0 (100.0)	2.3 (100.0)	0	6.2 (73.3)	1.3 (100.0)	0
Missing	0	0	0	0	0	0
Intrauterine balloon after conjoint period, N (%)						
Yes	0	0	0	0	0	0
No	5.0 (100.0)	2.3 (100.0)	0	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0
Other tamponade after conjoint period, N (%)						
Yes	0	0	0	0	0	0
No	5.0 (100.0)	2.3 (100.0)	0	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0
Removal of placenta after conjoint period, N (%)						
Yes	0	0	0	0	0	0
No	5.0 (100.0)	2.3 (100.0)	0	8.4 (100.0)	1.3 (100.0)	1.0 (100.0)
Missing	0	0	0	0	0	0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.2.74 Clinical outcomes - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure	After first invasive procedure	Missing
1.0 Number of patients	2	0	15	1	0
Hysterectomy in conjoint period, N (%)					
Yes	0	0	0	0	0
No	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Missing	0	0	0	0	0
Other invasive procedure(s) in conjoint period, N (%)					
Yes	0	0	4 (26.7)	0	0
No	2 (100.0)	0	11 (73.3)	1 (100.0)	0
Missing	0	0	0	0	0
Hysterectomy and other invasive procedure(s) in conjoint period, N (%)					
Yes	0	0	0	0	0
No	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Missing	0	0	0	0	0
Any invasive procedure(s) in conjoint period, N (%)					
Yes	0	0	4 (26.7)	0	0
No	2 (100.0)	0	11 (73.3)	1 (100.0)	0
Missing	0	0	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure	After first invasive procedure	Missing
Laparotomy in conjoint period, N (%)					
Yes	0	0	2 (13.3)	0	0
No	2 (100.0)	0	13 (86.7)	1 (100.0)	0
Missing	0	0	0	0	0
Intrauterine balloon in conjoint period, N (%)					
Yes	0	0	0	0	0
No	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Missing	0	0	0	0	0
Other tamponade in conjoint period, N (%)					
Yes	0	0	0	0	0
No	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Missing	0	0	0	0	0
Removal of placenta in conjoint period, N (%)					
Yes	0	0	0	0	0
No	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Missing	0	0	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure	After first invasive procedure	Missing
Hysterectomy after conjoint period, N (%)					
Yes	0	0	1 (6.7)	1 (100.0)	0
No	2 (100.0)	0	14 (93.3)	0	0
Missing	0	0	0	0	0
Other invasive procedure(s) after conjoint period, N (%)					
Yes	0	0	1 (6.7)	0	0
No	2 (100.0)	0	14 (93.3)	1 (100.0)	0
Missing	0	0	0	0	0
Hysterectomy and other invasive procedure(s) after conjoint period, N (%)					
Yes	0	0	0	0	0
No	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Missing	0	0	0	0	0
Any invasive procedure(s) after conjoint period, N (%)					
Yes	0	0	2 (13.3)	1 (100.0)	0
No	2 (100.0)	0	13 (86.7)	0	0
Missing	0	0	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure	After first invasive procedure	Missing
Laparotomy after conjoint period, N (%)					
Yes	0	0	0	1 (100.0)	0
No	2 (100.0)	0	15 (100.0)	0	0
Missing	0	0	0	0	0
Intrauterine balloon after conjoint period, N (%)					
Yes	0	0	0	0	0
No	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Missing	0	0	0	0	0
Other tamponade after conjoint period, N (%)					
Yes	1 (50.0)	0	0	0	0
No	1 (50.0)	0	15 (100.0)	1 (100.0)	0
Missing	0	0	0	0	0
Removal of placenta after conjoint period, N (%)					
Yes	0	0	0	0	0
No	2 (100.0)	0	15 (100.0)	1 (100.0)	0
Missing	0	0	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.2.75 Clinical outcomes - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Number of patients	4	14
Hysterectomy in conjoint period, N (%)		
Yes	0	0
No	4 (100.0)	14 (100.0)
Missing	0	0
Other invasive procedure(s) in conjoint period, N (%)		
Yes	3 (75.0)	1 (7.1)
No	1 (25.0)	13 (92.9)
Missing	0	0
Hysterectomy and other invasive procedure(s) in conjoint period, N (%)		
Yes	0	0
No	4 (100.0)	14 (100.0)
Missing	0	0
Any invasive procedure(s) in conjoint period, N (%)		
Yes	3 (75.0)	1 (7.1)
No	1 (25.0)	13 (92.9)
Missing	0	0

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Laparotomy in conjoint period, N (%)		
Yes	1 (25.0)	1 (7.1)
No	3 (75.0)	13 (92.9)
Missing	0	0
Intrauterine balloon in conjoint period, N (%)		
Yes	0	0
No	4 (100.0)	14 (100.0)
Missing	0	0
Other tamponade in conjoint period, N (%)		
Yes	0	0
No	4 (100.0)	14 (100.0)
Missing	0	0
Removal of placenta in conjoint period, N (%)		
Yes	0	0
No	4 (100.0)	14 (100.0)
Missing	0	0

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Hysterectomy after conjoint period, N (%)		
Yes	0	2 (14.3)
No	4 (100.0)	12 (85.7)
Missing	0	0
Other invasive procedure(s) after conjoint period, N (%)		
Yes	0	1 (7.1)
No	4 (100.0)	13 (92.9)
Missing	0	0
Hysterectomy and other invasive procedure(s) after conjoint period, N (%)		
Yes	0	0
No	4 (100.0)	14 (100.0)
Missing	0	0
Any invasive procedure(s) after conjoint period, N (%)		
Yes	0	3 (21.4)
No	4 (100.0)	11 (78.6)
Missing	0	0

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Laparotomy after conjoint period, N (%)		
Yes	0	1 (7.1)
No	4 (100.0)	13 (92.9)
Missing	0	0
Intrauterine balloon after conjoint period, N (%)		
Yes	0	0
No	4 (100.0)	14 (100.0)
Missing	0	0
Other tamponade after conjoint period, N (%)		
Yes	0	1 (7.1)
No	4 (100.0)	13 (92.9)
Missing	0	0
Removal of placenta after conjoint period, N (%)		
Yes	0	0
No	4 (100.0)	14 (100.0)
Missing	0	0

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.2.76 Clinical outcomes - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Number of patients	2	16	0
Hysterectomy in conjoint period, N (%)			
Yes	0	0	0
No	2 (100.0)	16 (100.0)	0
Missing	0	0	0
Other invasive procedure(s) in conjoint period, N (%)			
Yes	1 (50.0)	3 (18.8)	0
No	1 (50.0)	13 (81.3)	0
Missing	0	0	0
Hysterectomy and other invasive procedure(s) in conjoint period, N (%)			
Yes	0	0	0
No	2 (100.0)	16 (100.0)	0
Missing	0	0	0
Any invasive procedure(s) in conjoint period, N (%)			
Yes	1 (50.0)	3 (18.8)	0
No	1 (50.0)	13 (81.3)	0
Missing	0	0	0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Laparotomy in conjoint period, N (%)			
Yes	1 (50.0)	1 (6.3)	0
No	1 (50.0)	15 (93.8)	0
Missing	0	0	0
Intrauterine balloon in conjoint period, N (%)			
Yes	0	0	0
No	2 (100.0)	16 (100.0)	0
Missing	0	0	0
Other tamponade in conjoint period, N (%)			
Yes	0	0	0
No	2 (100.0)	16 (100.0)	0
Missing	0	0	0
Removal of placenta in conjoint period, N (%)			
Yes	0	0	0
No	2 (100.0)	16 (100.0)	0
Missing	0	0	0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Hysterectomy after conjoint period, N (%)			
Yes	1 (50.0)	1 (6.3)	0
No	1 (50.0)	15 (93.8)	0
Missing	0	0	0
Other invasive procedure(s) after conjoint period, N (%)			
Yes	0	1 (6.3)	0
No	2 (100.0)	15 (93.8)	0
Missing	0	0	0
Hysterectomy and other invasive procedure(s) after conjoint period, N (%)			
Yes	0	0	0
No	2 (100.0)	16 (100.0)	0
Missing	0	0	0
Any invasive procedure(s) after conjoint period, N (%)			
Yes	1 (50.0)	2 (12.5)	0
No	1 (50.0)	14 (87.5)	0
Missing	0	0	0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Laparotomy after conjoint period, N (%)			
Yes	1 (50.0)	0	0
No	1 (50.0)	16 (100.0)	0
Missing	0	0	0
Intrauterine balloon after conjoint period, N (%)			
Yes	0	0	0
No	2 (100.0)	16 (100.0)	0
Missing	0	0	0
Other tamponade after conjoint period, N (%)			
Yes	0	1 (6.3)	0
No	2 (100.0)	15 (93.8)	0
Missing	0	0	0
Removal of placenta after conjoint period, N (%)			
Yes	0	0	0
No	2 (100.0)	16 (100.0)	0
Missing	0	0	0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.2.77 Clinical outcomes - by gestational age for patients exposed NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	2	11	5	0
Hysterectomy in conjoint period, N (%)				
Yes	0	0	0	0
No	2 (100.0)	11 (100.0)	5 (100.0)	0
Missing	0	0	0	0
Other invasive procedure(s) in conjoint period, N (%)				
Yes	1 (50.0)	3 (27.3)	0	0
No	1 (50.0)	8 (72.7)	5 (100.0)	0
Missing	0	0	0	0
Hysterectomy and other invasive procedure(s) in conjoint period, N (%)				
Yes	0	0	0	0
No	2 (100.0)	11 (100.0)	5 (100.0)	0
Missing	0	0	0	0
Any invasive procedure(s) in conjoint period, N (%)				
Yes	1 (50.0)	3 (27.3)	0	0
No	1 (50.0)	8 (72.7)	5 (100.0)	0
Missing	0	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by gestational age for patients exposed NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Laparotomy in conjoint period, N (%)				
Yes	0	2 (18.2)	0	0
No	2 (100.0)	9 (81.8)	5 (100.0)	0
Missing	0	0	0	0
Intrauterine balloon in conjoint period, N (%)				
Yes	0	0	0	0
No	2 (100.0)	11 (100.0)	5 (100.0)	0
Missing	0	0	0	0
Other tamponade in conjoint period, N (%)				
Yes	0	0	0	0
No	2 (100.0)	11 (100.0)	5 (100.0)	0
Missing	0	0	0	0
Removal of placenta in conjoint period, N (%)				
Yes	0	0	0	0
No	2 (100.0)	11 (100.0)	5 (100.0)	0
Missing	0	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by gestational age for patients exposed NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Hysterectomy after conjoint period, N (%)				
Yes	0	2 (18.2)	0	0
No	2 (100.0)	9 (81.8)	5 (100.0)	0
Missing	0	0	0	0
Other invasive procedure(s) after conjoint period, N (%)				
Yes	0	0	1 (20.0)	0
No	2 (100.0)	11 (100.0)	4 (80.0)	0
Missing	0	0	0	0
Hysterectomy and other invasive procedure(s) after conjoint period, N (%)				
Yes	0	0	0	0
No	2 (100.0)	11 (100.0)	5 (100.0)	0
Missing	0	0	0	0
Any invasive procedure(s) after conjoint period, N (%)				
Yes	0	2 (18.2)	1 (20.0)	0
No	2 (100.0)	9 (81.8)	4 (80.0)	0
Missing	0	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by gestational age for patients exposed NovoSeven® - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Laparotomy after conjoint period, N (%)				
Yes	0	1 (9.1)	0	0
No	2 (100.0)	10 (90.9)	5 (100.0)	0
Missing	0	0	0	0
Intrauterine balloon after conjoint period, N (%)				
Yes	0	0	0	0
No	2 (100.0)	11 (100.0)	5 (100.0)	0
Missing	0	0	0	0
Other tamponade after conjoint period, N (%)				
Yes	0	0	1 (20.0)	0
No	2 (100.0)	11 (100.0)	4 (80.0)	0
Missing	0	0	0	0
Removal of placenta after conjoint period, N (%)				
Yes	0	0	0	0
No	2 (100.0)	11 (100.0)	5 (100.0)	0
Missing	0	0	0	0

PS: Propensity score, N: Number of patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.2.78 Clinical outcomes - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	1	26	16	0
Number of weighted patients, N	0.3	8.1	9.7	0
Hysterectomy in conjoint period, N (%)				
Yes	0	0	0	0
No	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
Missing	0	0	0	0
Other invasive procedure(s) in conjoint period, N (%)				
Yes	0.3 (100.0)	1.8 (21.6)	0.5 (5.2)	0
No	0	6.3 (78.4)	9.2 (94.8)	0
Missing	0	0	0	0
Hysterectomy and other invasive procedure(s) in conjoint period, N (%)				
Yes	0	0.3 (3.1)	0	0
No	0.3 (100.0)	7.8 (96.9)	9.7 (100.0)	0
Missing	0	0	0	0
Any invasive procedure(s) in conjoint period, N (%)				
Yes	0.3 (100.0)	2.0 (24.7)	0.5 (5.2)	0
No	0	6.1 (75.3)	9.2 (94.8)	0
Missing	0	0	0	0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Laparotomy in conjoint period, N (%)				
Yes	0	0.5 (6.2)	0.3 (3.4)	0
No	0.3 (100.0)	7.6 (93.8)	9.3 (96.6)	0
Missing	0	0	0	0
Intrauterine balloon in conjoint period, N (%)				
Yes	0	0.3 (3.1)	0	0
No	0.3 (100.0)	7.8 (96.9)	9.7 (100.0)	0
Missing	0	0	0	0
Other tamponade in conjoint period, N (%)				
Yes	0	0	1.0 (10.3)	0
No	0.3 (100.0)	8.1 (100.0)	8.7 (89.7)	0
Missing	0	0	0	0
Removal of placenta in conjoint period, N (%)				
Yes	0	0	0	0
No	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
Missing	0	0	0	0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Hysterectomy after conjoint period, N (%)				
Yes	0.3 (100.0)	1.0 (12.4)	0.6 (6.0)	0
No	0	7.1 (87.6)	9.1 (94.0)	0
Missing	0	0	0	0
Other invasive procedure(s) after conjoint period, N (%)				
Yes	0	0.5 (6.2)	2.0 (20.7)	0
No	0.3 (100.0)	7.6 (93.8)	7.7 (79.3)	0
Missing	0	0	0	0
Hysterectomy and other invasive procedure(s) after conjoint period, N (%)				
Yes	0	0	1.3 (12.9)	0
No	0.3 (100.0)	8.1 (100.0)	8.4 (87.1)	0
Missing	0	0	0	0
Any invasive procedure(s) after conjoint period, N (%)				
Yes	0.3 (100.0)	1.5 (18.6)	3.8 (39.7)	0
No	0	6.6 (81.4)	5.8 (60.3)	0
Missing	0	0	0	0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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Clinical outcomes - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Laparotomy after conjoint period, N (%)				
Yes	0	0.5 (6.2)	2.8 (28.4)	0
No	0.3 (100.0)	7.6 (93.8)	6.9 (71.6)	0
Missing	0	0	0	0
Intrauterine balloon after conjoint period, N (%)				
Yes	0	0	0	0
No	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
Missing	0	0	0	0
Other tamponade after conjoint period, N (%)				
Yes	0	0	0	0
No	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
Missing	0	0	0	0
Removal of placenta after conjoint period, N (%)				
Yes	0	0	0	0
No	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
Missing	0	0	0	0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients.

Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures and hysterectomy. *The groups hysterectomy, Other invasive procedure(s), hysterectomy and other invasive procedure(s) are mutually exclusive. In conjoint period is defined as 20 min before and after time0, After conjoint period is defined as the period from 20 min after time0 to 24 hours after time0. Other tamponade: nalador tamponade, intrauterine tamponade and vaginal tamponade.

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14.2.79 Hospital information - full analysis set

PS analysis set			Full analysis set		
	NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total
1.0 Number of patients	18	43	52	113	165
Stay in ICU or PACU, N (%)					
N	18 (100.0)	18.0 (100.0)	52 (100.0)	113 (100.0)	165 (100.0)
Yes	6 (33.3)	9.0 (50.0)	27 (51.9)	26 (23.0)	53 (32.1)
No	7 (38.9)	3.6 (19.9)	11 (21.2)	76 (67.3)	87 (52.7)
Missing	5 (27.8)	5.4 (30.1)	14 (26.9)	11 (9.7)	25 (15.2)
Time in ICU or PACU (hours)					
N	6	9.0	27	26	53
Mean (SD)	12.83 (7.39)	11.98 (4.38)	18.32 (21.47)	11.64 (7.43)	15.04 (16.38)
Median (IQR)	12.00 (8.00 - 18.00)	12.00 (6.00 - 16.00)	12.00 (8.00 - 18.50)	9.13 (5.59 - 18.00)	12.00 (6.10 - 18.00)
Min ; Max	3.0 ; 24.0	4.0 ; 24.0	3.0 ; 104.0	2.5 ; 24.0	2.5 ; 104.0
Duration of hospitalisation after onset of sPPH (days)					
N	18	18.0	52	101	153
Mean (SD)	9.09 (3.72)	9.64 (4.75)	9.37 (5.32)	5.62 (6.49)	6.90 (6.36)
Median (IQR)	7.50 (6.40 - 12.00)	8.50 (6.00 - 11.40)	8.50 (6.45 - 11.35)	4.50 (3.40 - 6.50)	5.40 (3.50 - 8.50)
Min ; Max	4.5 ; 16.0	2.0 ; 59.0	2.0 ; 31.9	0.4 ; 59.0	0.4 ; 59.0

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, ICU: intensive care unit, PACU: Post anaesthesia care unit.

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14.2.80 Hospital information - by concomitant use before time0 for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	7	7	1	3
Stay in ICU or PACU, N (%)				
N	7 (100.0)	7 (100.0)	1 (100.0)	3 (100.0)
Yes	4 (57.1)	1 (14.3)	0	1 (33.3)
No	2 (28.6)	4 (57.1)	0	1 (33.3)
Missing	1 (14.3)	2 (28.6)	1 (100.0)	1 (33.3)
Time in ICU or PACU (hours)				
N	4	1	0	1
Mean (SD)	14.25 (8.96)	12.00 (NE)		8.00 (NE)
Median (IQR)	15.00 (7.50 - 21.00)	12.00 (12.00 - 12.00)		8.00 (8.00 - 8.00)
Min ; Max	3.0 ; 24.0	12.0 ; 12.0		8.0 ; 8.0
Duration of hospitalisation after onset of sPPH (days)				
N	7	7	1	3
Mean (SD)	7.07 (2.40)	9.34 (4.42)	9.30 (NE)	13.17 (1.61)
Median (IQR)	6.40 (5.50 - 10.40)	6.50 (6.50 - 15.40)	9.30 (9.30 - 9.30)	12.50 (12.00 - 15.00)
Min ; Max	4.5 ; 10.5	6.0 ; 16.0	9.3 ; 9.3	12.0 ; 15.0

PS: Propensity score, TXA: Tranexamic acid, N: Number of patients, %: Percentage of patients, ICU: intensive care unit, PACU: Post anaesthesia care unit, NE: Not Estimable.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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14.2.81 Hospital information - by concomitant use before time0 for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	16	18	1	8
Stay in ICU or PACU, N (%)				
N	5.2 (100.0)	8.8 (100.0)	1.0 (100.0)	3.1 (100.0)
Yes	3.1 (59.7)	4.1 (46.7)	0	1.8 (59.5)
No	1.8 (35.5)	1.3 (14.3)	0	0.5 (16.2)
Missing	0.3 (4.8)	3.4 (39.0)	1.0 (100.0)	0.8 (24.3)
Time in ICU or PACU (hours)				
N	3.1	4.1	0	1.8
Mean (SD)	11.96 (3.30)	9.70 (3.72)		17.09 (6.48)
Median (IQR)	12.00 (8.00 - 16.00)	9.00 (6.00 - 12.00)		24.00 (8.00 - 24.00)
Min ; Max	5.0 ; 22.0	4.0 ; 24.0		4.0 ; 24.0
Duration of hospitalisation after onset of sPPH (days)				
N	5.2	8.8	1.0	3.1
Mean (SD)	6.27 (1.20)	10.72 (6.73)	9.30 (NE)	12.36 (2.99)
Median (IQR)	6.50 (4.50 - 7.40)	8.90 (6.50 - 13.50)	9.30 (9.30 - 9.30)	11.40 (9.70 - 12.00)
Min ; Max	2.5 ; 12.5	2.0 ; 59.0	9.3 ; 9.3	6.0 ; 24.0

PS: Propensity score, TXA: Tranexamic acid, N: Number of (weighted) patients, %: Percentage of patients, ICU: intensive care unit, PACU: Post anaesthesia care unit, NE: Not Estimable.

Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=) time0.

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14.2.82 Hospital information - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony
Number of patients	4	1	0	13
Stay in ICU or PACU, N (%)				
N	4 (100.0)	1 (100.0)	0	13 (100.0)
Yes	2 (50.0)	0	0	4 (30.8)
No	1 (25.0)	1 (100.0)	0	5 (38.5)
Missing	1 (25.0)	0	0	4 (30.8)
Time in ICU or PACU (hours)				
N	2	0	0	4
Mean (SD)	7.50 (6.36)			15.50 (7.00)
Median (IQR)	7.50 (3.00 - 12.00)			15.00 (10.00 - 21.00)
Min ; Max	3.0 ; 12.0			8.0 ; 24.0
Duration of hospitalisation after onset of sPPH (days)				
N	4	1	0	13
Mean (SD)	10.58 (5.97)	5.70 (NE)		8.90 (3.00)
Median (IQR)	10.90 (5.45 - 15.70)	5.70 (5.70 - 5.70)		8.50 (6.50 - 10.50)
Min ; Max	4.5 ; 16.0	5.7 ; 5.7		5.5 ; 15.0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, ICU: intensive care unit, PACU: Post anaesthesia care unit, NE: Not Estimable.

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Hospital information - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	Trauma	Other
Number of patients	0	0
Stay in ICU or PACU, N (%)		
N	0	0
Yes	0	0
No	0	0
Missing	0	0
Time in ICU or PACU (hours)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Duration of hospitalisation after onset of sPPH (days)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, ICU: intensive care unit, PACU: Post anaesthesia care unit, NE: Not Estimable.

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14.2.83 Hospital information - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine Atony
Number of patients	14	3	0	23
Stay in ICU or PACU, N (%)				
N	5.0 (100.0)	2.3 (100.0)	0	8.4 (100.0)
Yes	2.8 (56.7)	1.0 (44.4)	0	4.2 (49.5)
No	1.3 (26.7)	0.3 (11.1)	0	2.0 (23.8)
Missing	0.8 (16.7)	1.0 (44.4)	0	2.3 (26.7)
Time in ICU or PACU (hours)				
N	2.8	1.0	0	4.2
Mean (SD)	10.69 (4.49)	12.00 (NE)		13.57 (4.69)
Median (IQR)	6.00 (6.00 - 16.00)	12.00 (12.00 - 12.00)		14.00 (6.50 - 17.30)
Min ; Max	5.6 ; 24.0	12.0 ; 12.0		4.0 ; 24.0
Duration of hospitalisation after onset of sPPH (days)				
N	5.0	2.3	0	8.4
Mean (SD)	12.01 (7.33)	8.61 (7.10)		8.66 (2.08)
Median (IQR)	8.90 (6.50 - 15.40)	5.50 (2.00 - 16.00)		9.30 (6.00 - 11.40)
Min ; Max	3.5 ; 59.0	2.0 ; 16.0		2.5 ; 18.0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, ICU: intensive care unit, PACU: Post anaesthesia care unit, NE: Not Estimable.

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Hospital information - by cause of PPH for matched controls - PS analysis set

	Trauma	Other
Number of patients	2	1
Stay in ICU or PACU, N (%)		
N	1.3 (100.0)	1.0 (100.0)
Yes	1.0 (75.0)	0
No	0	0
Missing	0.3 (25.0)	1.0 (100.0)
Time in ICU or PACU (hours)		
N	1.0	0
Mean (SD)	9.00 (NE)	
Median (IQR)	9.00 (9.00 - 9.00)	
Min ; Max	9.0 ; 9.0	
Duration of hospitalisation after onset of sPPH (days)		
N	1.3	1.0
Mean (SD)	9.60 (3.40)	8.50 (NE)
Median (IQR)	11.30 (7.90 - 11.30)	8.50 (8.50 - 8.50)
Min ; Max	4.5 ; 11.3	8.5 ; 8.5

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, ICU: intensive care unit, PACU: Post anaesthesia care unit, NE: Not Estimable.

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14.2.84 Hospital information - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
1.0 Number of patients	2	0	15
Stay in ICU or PACU, N (%)			
N	2 (100.0)	0	15 (100.0)
Yes	2 (100.0)	0	4 (26.7)
No	0	0	7 (46.7)
Missing	0	0	4 (26.7)
Time in ICU or PACU (hours)			
N	2	0	4
Mean (SD)	7.50 (6.36)		15.50 (7.00)
Median (IQR)	7.50 (3.00 - 12.00)		15.00 (10.00 - 21.00)
Min ; Max	3.0 ; 12.0		8.0 ; 24.0
Duration of hospitalisation after onset of sPPH (days)			
N	2	0	15
Mean (SD)	6.20 (0.28)		9.29 (3.87)
Median (IQR)	6.20 (6.00 - 6.40)		8.50 (6.50 - 12.50)
Min ; Max	6.0 ; 6.4		4.5 ; 16.0

PS: Propensity score, N: Number of patients, %: Percentage of patients, ICU: intensive care unit, PACU: Post anaesthesia care unit, NE: Not Estimable.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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Hospital information - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® - PS analysis set

	After first invasive procedure	Missing
1.0 Number of patients	1	0
Stay in ICU or PACU, N (%)		
N	1 (100.0)	0
Yes	0	0
No	0	0
Missing	1 (100.0)	0
Time in ICU or PACU (hours)		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Duration of hospitalisation after onset of sPPH (days)		
N	1	0
Mean (SD)	12.00 (NE)	
Median (IQR)	12.00 (12.00 - 12.00)	
Min ; Max	12.0 ; 12.0	

PS: Propensity score, N: Number of patients, %: Percentage of patients, ICU: intensive care unit, PACU: Post anaesthesia care unit, NE: Not Estimable.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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14.2.85 Hospital information - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

< 30 minutes after onset of sPPH >= 30 minutes after onset of sPPH

Number of patients	4	14
Stay in ICU or PACU, N (%)		
N	4 (100.0)	14 (100.0)
Yes	1 (25.0)	5 (35.7)
No	2 (50.0)	5 (35.7)
Missing	1 (25.0)	4 (28.6)
Time in ICU or PACU (hours)		
N	1	5
Mean (SD)	18.00 (NE)	11.80 (7.76)
Median (IQR)	18.00 (18.00 - 18.00)	12.00 (8.00 - 12.00)
Min ; Max	18.0 ; 18.0	3.0 ; 24.0
Duration of hospitalisation after onset of sPPH (days)		
N	4	14
Mean (SD)	7.30 (2.17)	9.61 (3.97)
Median (IQR)	6.50 (6.10 - 8.50)	8.90 (6.40 - 12.50)
Min ; Max	5.7 ; 10.5	4.5 ; 16.0

sPPH: Severe postpartum haemorrhage, PS: Propensity score, N: Number of patients, %: Percentage of patients, ICU: intensive care unit, PACU: Post anaesthesia care unit, NE: Not Estimable.

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14.2.86 Hospital information - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Number of patients	2	16	0
Stay in ICU or PACU, N (%)			
N	2 (100.0)	16 (100.0)	0
Yes	0	6 (37.5)	0
No	1 (50.0)	6 (37.5)	0
Missing	1 (50.0)	4 (25.0)	0
Time in ICU or PACU (hours)			
N	0	6	0
Mean (SD)		12.83 (7.39)	
Median (IQR)		12.00 (8.00 - 18.00)	
Min ; Max		3.0 ; 24.0	
Duration of hospitalisation after onset of sPPH (days)			
N	2	16	0
Mean (SD)	8.85 (4.45)	9.13 (3.79)	
Median (IQR)	8.85 (5.70 - 12.00)	7.50 (6.45 - 11.50)	
Min ; Max	5.7 ; 12.0	4.5 ; 16.0	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, ICU: intensive care unit, PACU: Post anaesthesia care unit, NE: Not Estimable.

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14.2.87 Hospital information - by gestational age for patients exposed to NovoSeven® - PS matched analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	2	11	5	0
Stay in ICU or PACU, N (%)				
N	2 (100.0)	11 (100.0)	5 (100.0)	0
Yes	1 (50.0)	2 (18.2)	3 (60.0)	0
No	0	6 (54.5)	1 (20.0)	0
Missing	1 (50.0)	3 (27.3)	1 (20.0)	0
Time in ICU or PACU (hours)				
N	1	2	3	0
Mean (SD)	12.00 (NE)	15.00 (4.24)	11.67 (10.97)	
Median (IQR)	12.00 (12.00 - 12.00)	15.00 (12.00 - 18.00)	8.00 (3.00 - 24.00)	
Min ; Max	12.0 ; 12.0	12.0 ; 18.0	3.0 ; 24.0	
Duration of hospitalisation after onset of sPPH (days)				
N	2	11	5	0
Mean (SD)	6.25 (0.35)	9.42 (4.09)	9.52 (3.53)	
Median (IQR)	6.25 (6.00 - 6.50)	8.50 (5.70 - 12.50)	9.30 (6.50 - 10.40)	
Min ; Max	6.0 ; 6.5	4.5 ; 16.0	6.4 ; 15.0	

PS: Propensity score, N: Number of patients, %: Percentage of patients, ICU: intensive care unit, PACU: Post anaesthesia care unit, NE: Not Estimable.

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14.2.88 Hospital information - by gestational age for matched controls - PS matched analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	1	26	16	0
Stay in ICU or PACU, N (%)				
N	0.3 (100.0)	8.1 (100.0)	9.7 (100.0)	0
Yes	0.3 (100.0)	2.8 (35.1)	5.9 (61.2)	0
No	0	2.8 (35.1)	0.8 (7.8)	0
Missing	0	2.4 (29.9)	3.0 (31.0)	0
Time in ICU or PACU (hours)				
N	0.3	2.8	5.9	0
Mean (SD)	8.00 (NE)	11.82 (4.16)	12.22 (4.90)	
Median (IQR)	8.00 (8.00 - 8.00)	12.00 (6.00 - 16.00)	12.00 (8.00 - 17.30)	
Min ; Max	8.0 ; 8.0	4.0 ; 24.0	4.0 ; 24.0	
Duration of hospitalisation after onset of sPPH (days)				
N	0.3	8.1	9.7	0
Mean (SD)	6.50 (NE)	10.97 (5.55)	8.61 (3.15)	
Median (IQR)	6.50 (6.50 - 6.50)	8.90 (6.50 - 12.50)	8.50 (6.00 - 11.30)	
Min ; Max	6.5 ; 6.5	2.5 ; 59.0	2.0 ; 16.0	

PS: Propensity score, N: Number of (weighted) patients, %: Percentage of patients, ICU: intensive care unit, PACU: Post anaesthesia care unit, NE: Not Estimable.

/fvii/nn7711-4729/ctr_20210821_er
18AUG2021:14:43:59 - tsumhosp.sas/tsumhospgagectrlpsas.txt

14.2.89 Invasive procedures – full analysis set

	PS analysis set	Full analysis set
	NovoSeven®	NovoSeven®
Number of patients, N	18	52
Number of patients censored *, N	0	13
Number of patients not censored, N (%)	18 (100.0)	39 (100.0)
Received an invasive procedure after conjoint period in patients not censored, N (%)	3 (16.7)	8 (20.5)
Number of patients not censored and without invasive procedure prior to NovoSeven®, N (%)	3 (100.0)	12 (100.0)
Received an invasive procedure after conjoint period in patients not censored and did not receive an invasive procedure prior to NovoSeven®, N (%)	1 (33.3)	2 (16.7)

N: Number of patients, %: Percentage of patients, *Patients censored: Patients who hysterectomised before or in conjoint period with NovoSeven® administration, or patients who had PPH (postpartum haemorrhage) stop before NovoSeven® administration.
For patients not censored, patients with other invasive procedures before or in conjoint period with NovoSeven® administration are included.
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14.2.90 NovoSeven® doses (µg/kg) - by first dose of NovoSeven® (µg/kg) - full analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Number of patients	14	37	1
Total number of NovoSeven® doses per patient, N (%)			
N	14 (100.0)	37 (100.0)	1 (100.0)
1 dose	10 (71.4)	35 (94.6)	1 (100.0)
2 doses	4 (28.6)	2 (5.4)	0
1st dose of NovoSeven® (µg/kg)			
N	14	37	1
Mean (SD)	44.1 (15.7)	68.1 (6.7)	121.2 (NE)
Median (IQR)	53.1 (33.9 - 54.5)	65.5 (62.5 - 73.5)	121.2 (121.2 - 121.2)
Min ; Max	12.0 ; 57.5	60.6 ; 84.7	121.2 ; 121.2
2nd dose of NovoSeven® (µg/kg)			
N	4	2	0
Mean (SD)	68.0 (16.3)	80.3 (6.4)	
Median (IQR)	68.2 (56.9 - 79.2)	80.3 (75.8 - 84.7)	
Min ; Max	48.0 ; 87.7	75.8 ; 84.7	

N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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NovoSeven® doses (µg/kg) - by first dose of NovoSeven® (µg/kg) - full analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Total dose of NovoSeven® (µg/kg)			
N	14	37	1
Mean (SD)	63.5 (25.4)	72.5 (22.2)	121.2 (NE)
Median (IQR)	55.0 (53.2 - 60.0)	65.5 (62.5 - 73.5)	121.2 (121.2 - 121.2)
Min ; Max	33.9 ; 123.5	60.6 ; 169.5	121.2 ; 121.2
Received only one dose (µg/kg)			
N	10	35	1
Mean (SD)	50.9 (8.3)	67.4 (6.1)	121.2 (NE)
Median (IQR)	54.5 (52.7 - 55.4)	64.3 (62.1 - 72.7)	121.2 (121.2 - 121.2)
Min ; Max	33.9 ; 57.5	60.6 ; 81.4	121.2 ; 121.2
1st dose of NovoSeven® (mg)			
N	14	37	1
Mean (SD)	3.3 (1.5)	4.6 (1.0)	8.0 (NE)
Median (IQR)	3.3 (2.0 - 4.8)	4.8 (4.0 - 5.0)	8.0 (8.0 - 8.0)
Min ; Max	1.0 ; 6.0	3.0 ; 8.0	8.0 ; 8.0
Total dose of NovoSeven® (mg)			
N	14	37	1
Mean (SD)	4.7 (1.9)	4.9 (1.6)	8.0 (NE)
Median (IQR)	4.9 (3.0 - 6.0)	4.8 (4.0 - 5.0)	8.0 (8.0 - 8.0)
Min ; Max	2.0 ; 8.4	3.0 ; 10.0	8.0 ; 8.0

N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable.

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14.3 Safety data

14.3.1 Displays of adverse events

14.3.1.1 Adverse events in women with an event of sPPH - full analysis set

	NovoSeven®			No NovoSeven®			Total		
	N	(%)	E	N	(%)	E	N	(%)	E
Number of patients	52			113			165		
Total thromboembolic events	0			1	(0.9)	1	1	(0.6)	1
Arterial thromboembolic event	0			0			0		
Venous thromboembolic event	0			1	(0.9)	1	1	(0.6)	1
Allergic reactions	2	(3.8)	2	0			2	(1.2)	2
Cardiac arrest	1	(1.9)	1	1	(0.9)	1	2	(1.2)	2
Haemorrhagic shock	6	(11.5)	6	4	(3.5)	5	10	(6.1)	11

N: Number of patients with events, %: Percentage of patients with events, E: Number of events.
 Number of patients with more than one event are counted once and number of events are counted as per their occurrences. TE are classified as arterial or venous by medical specialist.
 Refer individual listing 16.2.7.5 for haemorrhage shock details.

14.3.1.2 Adverse events in women with an event of sPPH - PS analysis set

	NovoSeven®			Matched Control		
	N	(%)	E	N	(%)	E
Number of patients	18			43		
Number of weighted patients, N				18.0		
Total thromboembolic events	0			0.3	(1.4)	1
Arterial thromboembolic event	0			0		
Venous thromboembolic event	0			0.3	(1.4)	1
Allergic reactions	1	(5.6)	1	0		
Cardiac arrest	0			0.3	(1.4)	1
Haemorrhagic shock	1	(5.6)	1	1.8	(10.2)	4

N: Number of patients with events, %: Percentage of patients with events, E: Number of events.

Number of patients with more than one event are counted once and number of events are counted as per their occurrences. TE are classified as arterial or venous by medical specialist.

Refer individual listing 16.2.7.5 for haemorrhage shock details.

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14.3.1.3 Maternal deaths during hospitalisation - full analysis set

	NovoSeven®		No NovoSeven®		Total	
	N	(%)	N	(%)	N	(%)
Number of patients	52		113		165	
Deaths	0		0		0	

N: Number of patients, %: Percentage of patients.

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18AUG2021:14:42:10 - tsumaedth.sas/tsumaedthfas.txt

14.3.1.4 Secondary endpoint - occurrence of thromboembolic events - statistical analysis - PS analysis set

	PSAS	N	Estimate	95% CI	p-value
Total TE					
NovoSeven®	18	0	0.0	[0.0 ; 18.5]	
Matched controls	43	0.0	0.0	[0.0 ; 18.5]	
NovoSeven®/ Matched controls	61		NE		
Arterial TE					
NovoSeven®	18	0	0.0	[0.0 ; 18.5]	
Matched controls	43	0.0	0.0	[0.0 ; 18.5]	
NovoSeven®/ Matched controls	61		NE		
Venous TE					
NovoSeven®	18	0	0.0	[0.0 ; 18.5]	
Matched controls	43	0.0	0.0	[0.0 ; 18.5]	
NovoSeven®/ Matched controls	61		NE		

PS: Propensity score, PSAS: Propensity score analysis set, N: Number of (weighted) patients with TEs, CI: Confidence interval, TE: Thromboembolic events, NE: Not estimable.

TE are classified as arterial or venous by medical specialist. The TEs occurring in the period from time0 until 5 days after time0 has been considered for statistics analysis. Imputed dates considered for occurrence of TE statistical analysis.

Relative risk estimates for occurrence of TEs were compared between NovoSeven® and Control (treatment ratio), using the two sided Fisher exact test method with a 95% exact confidence interval based on the propensity score matching, along with p-value.

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14.3.5 Laboratory value displays**14.3.5.1 Baseline laboratory parameters - full analysis set**

	PS analysis set		Full analysis set		
	NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total
Number of patients	18	43	52	113	165
Fibrinogen (g/L)					
Baseline					
N	7	3.9	22		
Mean (SD)	1.94 (0.68)	1.90 (0.54)	1.82 (0.69)		
Median (IQR)	2.15 (1.31 - 2.26)	1.88 (1.50 - 2.02)	1.66 (1.31 - 2.22)		
Min ; Max	1.25 ; 3.09	1.05 ; 3.76	0.80 ; 3.47		
No Fibrinogen dose given between baseline and time0					
N	6	3.9	20		
Mean (SD)	1.90 (0.74)	1.90 (0.54)	1.79 (0.72)		
Median (IQR)	1.74 (1.31 - 2.26)	1.88 (1.50 - 2.02)	1.51 (1.31 - 2.20)		
Min ; Max	1.25 ; 3.09	1.05 ; 3.76	0.80 ; 3.47		
Fibrinogen, N (%)					
Baseline					
N	7 (100.0)	3.9 (100.0)	22 (100.0)		
<2 g/L	3 (42.9)	2.8 (70.2)	12 (54.5)		
>=2 g/L	4 (57.1)	1.2 (29.8)	10 (45.5)		
No Fibrinogen dose given between baseline and time0, N (%)					
N	6 (100.0)	3.9 (100.0)	20 (100.0)		
<2 g/L	3 (50.0)	2.8 (70.2)	12 (60.0)		
>=2 g/L	3 (50.0)	1.2 (29.8)	8 (40.0)		

PS: Propensity Score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - full analysis set

		PS analysis set		Full analysis set	
		NovoSeven®	Matched controls	NovoSeven®	No NovoSeven® Total
1.0	Haemoglobin (g/L)				
	Baseline				
	N	8	6.4	29	
	Mean (SD)	82.5 (23.7)	76.4 (6.9)	81.1 (19.2)	
	Median (IQR)	84.5 (64.5 - 95.5)	75.0 (72.0 - 76.0)	82.0 (72.0 - 91.0)	
	Min ; Max	49 ; 122	65 ; 101	49 ; 126	
No RBC units given between baseline and time0					
	N	2	1.8	9	
	Mean (SD)	69.0 (18.4)	73.7 (2.4)	76.7 (16.4)	
	Median (IQR)	69.0 (56.0 - 82.0)	75.0 (74.0 - 75.0)	82.0 (63.0 - 91.0)	
	Min ; Max	56 ; 82	66 ; 76	49 ; 91	
Platelets (10 ⁹ /L)					
	Baseline				
	N	5	4.4	25	
	Mean (SD)	205.0 (260.9)	116.0 (40.2)	107.6 (125.9)	
	Median (IQR)	103.0 (86.0 - 122.0)	108.0 (55.0 - 155.0)	86.0 (51.0 - 106.0)	
	Min ; Max	45 ; 669	51 ; 223	27 ; 669	
No Platelets dose given between baseline and time0					
	N	4	3.4	16	
	Mean (SD)	234.8 (291.3)	135.0 (33.7)	119.5 (156.7)	
	Median (IQR)	112.5 (74.0 - 395.5)	119.0 (97.0 - 193.0)	68.0 (43.0 - 112.5)	
	Min ; Max	45 ; 669	55 ; 223	27 ; 669	

PS: Propensity Score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - full analysis set

		PS analysis set		Full analysis set		
		NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total
1.0	Platelets, N (%)					
	Baseline					
	N	5 (100.0)	4.4 (100.0)	25 (100.0)		
	<50 10 ⁹ /L	1 (20.0)	0	6 (24.0)		
	>=50 10 ⁹ /L	4 (80.0)	4.4 (100.0)	19 (76.0)		
	No Platelets dose given between baseline and time0, N (%)					
	N	4 (100.0)	3.4 (100.0)	16 (100.0)		
	<50 10 ⁹ /L	1 (25.0)	0	6 (37.5)		
	>=50 10 ⁹ /L	3 (75.0)	3.4 (100.0)	10 (62.5)		
	pH					
	Baseline					
	N	4	4.1	18		
	Mean (SD)	7.31 (0.06)	7.35 (0.10)	7.30 (0.09)		
	Median (IQR)	7.32 (7.27 - 7.35)	7.31 (7.21 - 7.40)	7.31 (7.27 - 7.35)		
	Min ; Max	7.23 ; 7.37	7.20 ; 7.54	7.06 ; 7.45		
	No Crystalloids and Colloids doses given between baseline and time0					
	N	4	3.8	17		
	Mean (SD)	7.31 (0.06)	7.36 (0.11)	7.31 (0.09)		
	Median (IQR)	7.32 (7.27 - 7.35)	7.31 (7.20 - 7.54)	7.32 (7.27 - 7.35)		
	Min ; Max	7.23 ; 7.37	7.20 ; 7.54	7.06 ; 7.45		

PS: Propensity Score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - full analysis set

		PS analysis set		Full analysis set		
		NovoSeven®	Matched controls	NovoSeven®	No NovoSeven®	Total
1.0	pH, N (%)					
	Baseline					
	N	4 (100.0)	4.1 (100.0)	18 (100.0)		
	<7.2	0	0	1 (5.6)		
	>=7.2	4 (100.0)	4.1 (100.0)	17 (94.4)		
No Crystalloids and Colloids doses given between baseline and time0, N (%)						
N		4 (100.0)	3.8 (100.0)	17 (100.0)		
<7.2		0	0	1 (5.9)		
>=7.2		4 (100.0)	3.8 (100.0)	16 (94.1)		
Body temperature (C)						
Baseline						
N		7	5.9	18		
Mean (SD)		36.46 (0.52)	36.70 (0.38)	36.63 (1.15)		
Median (IQR)		36.40 (36.30 - 37.00)	37.00 (36.20 - 37.00)	36.55 (36.20 - 37.00)		
Min ; Max		35.5 ; 37	35.3 ; 37.4	33.8 ; 38.8		

PS: Propensity Score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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14.3.5.2 Baseline laboratory parameters - by concomitant use for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	7	7	1	3
Fibrinogen (g/L)				
Baseline				
N	2	4	1	0
Mean (SD)	1.74 (0.69)	2.21 (0.72)	1.31 (NE)	
Median (IQR)	1.74 (1.25 - 2.22)	2.21 (1.74 - 2.68)	1.31 (1.31 - 1.31)	
Min ; Max	1.25 ; 2.22	1.33 ; 3.09	1.31 ; 1.31	
No Fibrinogen dose given between baseline and time0				
N	1	4	1	0
Mean (SD)	1.25 (NE)	2.21 (0.72)	1.31 (NE)	
Median (IQR)	1.25 (1.25 - 1.25)	2.21 (1.74 - 2.68)	1.31 (1.31 - 1.31)	
Min ; Max	1.25 ; 1.25	1.33 ; 3.09	1.31 ; 1.31	
Fibrinogen, N (%)				
Baseline				
N	2 (100.0)	4 (100.0)	1 (100.0)	0
<2 g/L	1 (50.0)	1 (25.0)	1 (100.0)	
>=2 g/L	1 (50.0)	3 (75.0)	0	
No Fibrinogen dose given between baseline and time0, N (%)				
N	1 (100.0)	4 (100.0)	1 (100.0)	0
<2 g/L	1 (100.0)	1 (25.0)	1 (100.0)	
>=2 g/L	0	3 (75.0)	0	

PS: Propensity Score, TXA: Tranexamic acid, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0. Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(=)/after(>) time0.

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Baseline laboratory parameters - by concomitant use for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Haemoglobin (g/L)				
Baseline				
N	3	4	0	1
Mean (SD)	88.3 (33.0)	80.5 (22.8)		73.0 (NE)
Median (IQR)	87.0 (56.0 - 122.0)	85.0 (65.5 - 95.5)		73.0 (73.0 - 73.0)
Min ; Max	56 ; 122	49 ; 103		73 ; 73
No RBC units given between baseline and time0				
N	1	1	0	0
Mean (SD)	56.0 (NE)	82.0 (NE)		
Median (IQR)	56.0 (56.0 - 56.0)	82.0 (82.0 - 82.0)		
Min ; Max	56 ; 56	82 ; 82		
Platelets (10 ⁹ /L)				
Baseline				
N	1	3	0	1
Mean (SD)	122.0 (NE)	266.7 (349.0)		103.0 (NE)
Median (IQR)	122.0 (122.0 - 122.0)	86.0 (45.0 - 669.0)		103.0 (103.0 - 103.0)
Min ; Max	122 ; 122	45 ; 669		103 ; 103
No Platelets dose given between baseline and time0				
N	1	2	0	1
Mean (SD)	122.0 (NE)	357.0 (441.2)		103.0 (NE)
Median (IQR)	122.0 (122.0 - 122.0)	357.0 (45.0 - 669.0)		103.0 (103.0 - 103.0)
Min ; Max	122 ; 122	45 ; 669		103 ; 103

PS: Propensity Score, TXA: Tranexamic acid, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0. Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(=)/after(>) time0.

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Baseline laboratory parameters - by concomitant use for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Platelets, N (%)				
Baseline				
N	1 (100.0)	3 (100.0)	0	1 (100.0)
<50 10 ⁹ /L	0	1 (33.3)		0
>=50 10 ⁹ /L	1 (100.0)	2 (66.7)		1 (100.0)
No Platelets dose given between baseline and time0, N (%)				
N	1 (100.0)	2 (100.0)	0	1 (100.0)
<50 10 ⁹ /L	0	1 (50.0)		0
>=50 10 ⁹ /L	1 (100.0)	1 (50.0)		1 (100.0)
pH				
Baseline				
N	2	1	1	0
Mean (SD)	7.35 (0.02)	7.23 (NE)	7.31 (NE)	
Median (IQR)	7.35 (7.34 - 7.37)	7.23 (7.23 - 7.23)	7.31 (7.31 - 7.31)	
Min ; Max	7.34 ; 7.37	7.23 ; 7.23	7.31 ; 7.31	
No Crystalloids and Colloids doses given between baseline and time0				
N	2	1	1	0
Mean (SD)	7.35 (0.02)	7.23 (NE)	7.31 (NE)	
Median (IQR)	7.35 (7.34 - 7.37)	7.23 (7.23 - 7.23)	7.31 (7.31 - 7.31)	
Min ; Max	7.34 ; 7.37	7.23 ; 7.23	7.31 ; 7.31	

PS: Propensity Score, TXA: Tranexamic acid, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0. Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=)/after(>) time0.

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Baseline laboratory parameters - by concomitant use for patients exposed to NovoSeven® - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
pH, N (%)				
Baseline				
N	2 (100.0)	1 (100.0)	1 (100.0)	0
<7.2	0	0	0	
>=7.2	2 (100.0)	1 (100.0)	1 (100.0)	
No Crystalloids and Colloids doses given between baseline and time0, N (%)				
N	2 (100.0)	1 (100.0)	1 (100.0)	0
<7.2	0	0	0	
>=7.2	2 (100.0)	1 (100.0)	1 (100.0)	
Body temperature (C)				
Baseline				
N	1	4	1	1
Mean (SD)	37.00 (NE)	36.30 (0.62)	36.70 (NE)	36.30 (NE)
Median (IQR)	37.00 (37.00 - 37.00)	36.35 (35.90 - 36.70)	36.70 (36.70 - 36.70)	36.30 (36.30 - 36.30)
Min ; Max	37.0 ; 37.0	35.5 ; 37.0	36.7 ; 36.7	36.3 ; 36.3

PS: Propensity Score, TXA: Tranexamic acid, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0. Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=)/after(>) time0.

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14.3.5.3 Baseline laboratory parameters - by concomitant use for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Number of patients	16	18	1	8
Fibrinogen (g/L)				
Baseline				
N	0.8	2.2	1.0	0
Mean (SD)	1.98 (0.05)	1.88 (0.77)	1.88 (NE)	
Median (IQR)	2.02 (1.89 - 2.02)	1.50 (1.50 - 2.40)	1.88 (1.88 - 1.88)	
Min ; Max	1.89 ; 2.02	1.05 ; 3.76	1.88 ; 1.88	
No Fibrinogen dose given between baseline and time0				
N	0.8	2.2	1.0	0
Mean (SD)	1.98 (0.05)	1.88 (0.77)	1.88 (NE)	
Median (IQR)	2.02 (1.89 - 2.02)	1.50 (1.50 - 2.40)	1.88 (1.88 - 1.88)	
Min ; Max	1.89 ; 2.02	1.05 ; 3.76	1.88 ; 1.88	
Fibrinogen, N (%)				
Baseline				
N	0.8 (100.0)	2.2 (100.0)	1.0 (100.0)	0
<2 g/L	0.3 (33.3)	1.5 (69.2)	1.0 (100.0)	
>=2 g/L	0.5 (66.7)	0.7 (30.8)	0	
No Fibrinogen dose given between baseline and time0, N (%)				
N	0.8 (100.0)	2.2 (100.0)	1.0 (100.0)	0
<2 g/L	0.3 (33.3)	1.5 (69.2)	1.0 (100.0)	
>=2 g/L	0.5 (66.7)	0.7 (30.8)	0	

PS: Propensity Score, TXA: Tranexamic acid, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0. Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=)/after(>) time0.

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Baseline laboratory parameters - by concomitant use for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Haemoglobin (g/L)				
Baseline				
N	2.5	2.7	1.0	0.3
Mean (SD)	78.9 (7.8)	74.6 (7.5)	75.0 (NE)	76.0 (NE)
Median (IQR)	75.5 (66.0 - 93.0)	72.0 (71.0 - 72.0)	75.0 (75.0 - 75.0)	76.0 (76.0 - 76.0)
Min ; Max	65 ; 97	66 ; 101	75 ; 75	76 ; 76
No RBC units given between baseline and time0				
N	0.5	0.3	1.0	0
Mean (SD)	71.0 (3.5)	74.0 (NE)	75.0 (NE)	
Median (IQR)	71.0 (66.0 - 76.0)	74.0 (74.0 - 74.0)	75.0 (75.0 - 75.0)	
Min ; Max	66 ; 76	74 ; 74	75 ; 75	
Platelets (10 ⁹ /L)				
Baseline				
N	2.0	2.2	0	0.3
Mean (SD)	117.8 (31.4)	109.9 (58.1)		155.0 (NE)
Median (IQR)	119.0 (81.5 - 144.0)	97.0 (51.0 - 193.0)		155.0 (155.0 - 155.0)
Min ; Max	55 ; 198	51 ; 223		155 ; 155
No Platelets dose given between baseline and time0				
N	2.0	1.2	0	0.3
Mean (SD)	117.8 (31.4)	160.4 (42.8)		155.0 (NE)
Median (IQR)	119.0 (81.5 - 144.0)	193.0 (97.0 - 223.0)		155.0 (155.0 - 155.0)
Min ; Max	55 ; 198	97 ; 223		155 ; 155

PS: Propensity Score, TXA: Tranexamic acid, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0. Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(=)/after(>) time0.

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Baseline laboratory parameters - by concomitant use for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
Platelets, N (%)				
Baseline				
N	2.0 (100.0)	2.2 (100.0)	0	0.3 (100.0)
<50 10 ⁹ /L	0	0		0
>=50 10 ⁹ /L	2.0 (100.0)	2.2 (100.0)		0.3 (100.0)
No Platelets dose given between baseline and time0, N (%)				
N	2.0 (100.0)	1.2 (100.0)	0	0.3 (100.0)
<50 10 ⁹ /L	0	0		0
>=50 10 ⁹ /L	2.0 (100.0)	1.2 (100.0)		0.3 (100.0)
pH				
Baseline				
N	0.8	2.3	1.0	0
Mean (SD)	7.32 (0.05)	7.28 (0.08)	7.54 (NE)	
Median (IQR)	7.38 (7.21 - 7.38)	7.31 (7.20 - 7.31)	7.54 (7.54 - 7.54)	
Min ; Max	7.21 ; 7.38	7.20 ; 7.40	7.54 ; 7.54	
No Crystalloids and Colloids doses given between baseline and time0				
N	0.5	2.3	1.0	0
Mean (SD)	7.38 (0.00)	7.28 (0.08)	7.54 (NE)	
Median (IQR)	7.38 (7.38 - 7.38)	7.31 (7.20 - 7.31)	7.54 (7.54 - 7.54)	
Min ; Max	7.38 ; 7.38	7.20 ; 7.40	7.54 ; 7.54	

PS: Propensity Score, TXA: Tranexamic acid, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0. Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=)/after(>) time0.

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Baseline laboratory parameters - by concomitant use for matched controls - PS analysis set

	Both TXA and Fibrinogen	Only TXA	Only Fibrinogen	No TXA and No Fibrinogen
pH, N (%)				
Baseline				
N	0.8 (100.0)	2.3 (100.0)	1.0 (100.0)	0
<7.2	0	0	0	
>=7.2	0.8 (100.0)	2.3 (100.0)	1.0 (100.0)	
No Crystalloids and Colloids doses given between baseline and time0, N (%)				
N	0.5 (100.0)	2.3 (100.0)	1.0 (100.0)	0
<7.2	0	0	0	
>=7.2	0.5 (100.0)	2.3 (100.0)	1.0 (100.0)	
Body temperature (C)				
Baseline				
N	1.3	2.9	1.0	0.8
Mean (SD)	36.26 (0.35)	36.92 (0.40)	37.00 (NE)	36.13 (0.06)
Median (IQR)	36.30 (36.30 - 36.40)	37.00 (36.70 - 37.40)	37.00 (37.00 - 37.00)	36.20 (36.00 - 36.20)
Min ; Max	35.3 ; 37.0	36.1 ; 37.4	37.0 ; 37.0	36.0 ; 36.2

PS: Propensity Score, TXA: Tranexamic acid, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0. Tranexamic acid (TXA) and/or Fibrinogen were considered as concomitant use when medications were administered 24 hours before(<=)/after(>) time0.

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14.3.5.4 Baseline laboratory parameters - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony
Number of patients	4	1	0	13
Fibrinogen (g/L)				
Baseline				
N	2	1	0	4
Mean (SD)	2.24 (0.03)	1.25 (NE)		1.97 (0.84)
Median (IQR)	2.24 (2.22 - 2.26)	1.25 (1.25 - 1.25)		1.74 (1.32 - 2.62)
Min ; Max	2.22 ; 2.26	1.25 ; 1.25		1.31 ; 3.09
No Fibrinogen dose given between baseline and time0				
N	1	1	0	4
Mean (SD)	2.26 (NE)	1.25 (NE)		1.97 (0.84)
Median (IQR)	2.26 (2.26 - 2.26)	1.25 (1.25 - 1.25)		1.74 (1.32 - 2.62)
Min ; Max	2.26 ; 2.26	1.25 ; 1.25		1.31 ; 3.09
Fibrinogen, N (%)				
Baseline				
N	2 (100.0)	1 (100.0)	0	4 (100.0)
<2 g/L	0	1 (100.0)		2 (50.0)
>=2 g/L	2 (100.0)	0		2 (50.0)
No Fibrinogen dose given between baseline and time0, N (%)				
N	1 (100.0)	1 (100.0)	0	4 (100.0)
<2 g/L	0	1 (100.0)		2 (50.0)
>=2 g/L	1 (100.0)	0		2 (50.0)

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	Trauma	Other
Number of patients	0	0
Fibrinogen (g/L)		
Baseline		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
No Fibrinogen dose given between baseline and time0		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Fibrinogen, N (%)		
Baseline		
N	0	0
<2 g/L		
>=2 g/L		
No Fibrinogen dose given between baseline and time0, N (%)		
N	0	0
<2 g/L		
>=2 g/L		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony
Haemoglobin (g/L)				
Baseline				
N	2	1	0	5
Mean (SD)	85.5 (51.6)	56.0 (NE)		86.6 (10.9)
Median (IQR)	85.5 (49.0 - 122.0)	56.0 (56.0 - 56.0)		87.0 (82.0 - 88.0)
Min ; Max	49 ; 122	56 ; 56		73 ; 103
No RBC units given between baseline and time0				
N	0	1	0	1
Mean (SD)		56.0 (NE)		82.0 (NE)
Median (IQR)		56.0 (56.0 - 56.0)		82.0 (82.0 - 82.0)
Min ; Max		56 ; 56		82 ; 82
Platelets (10 ⁹ /L)				
Baseline				
N	1	1	0	3
Mean (SD)	669.0 (NE)	122.0 (NE)		78.0 (29.8)
Median (IQR)	669.0 (669.0 - 669.0)	122.0 (122.0 - 122.0)		86.0 (45.0 - 103.0)
Min ; Max	669 ; 669	122 ; 122		45 ; 103
No Platelets dose given between baseline and time0				
N	1	1	0	2
Mean (SD)	669.0 (NE)	122.0 (NE)		74.0 (41.0)
Median (IQR)	669.0 (669.0 - 669.0)	122.0 (122.0 - 122.0)		74.0 (45.0 - 103.0)
Min ; Max	669 ; 669	122 ; 122		45 ; 103

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	Trauma	Other
Haemoglobin (g/L)		
Baseline		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
No RBC units given between baseline and time0		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Platelets (10 ⁹ /L)		
Baseline		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
No Platelets dose given between baseline and time0		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony
Platelets, N (%)				
Baseline				
N	1 (100.0)	1 (100.0)	0	3 (100.0)
<50 10 ⁹ /L	0	0		1 (33.3)
>=50 10 ⁹ /L	1 (100.0)	1 (100.0)		2 (66.7)
No Platelets dose given between baseline and time0, N (%)				
N	1 (100.0)	1 (100.0)	0	2 (100.0)
<50 10 ⁹ /L	0	0		1 (50.0)
>=50 10 ⁹ /L	1 (100.0)	1 (100.0)		1 (50.0)
pH				
Baseline				
N	1	0	0	3
Mean (SD)	7.37 (NE)			7.29 (0.06)
Median (IQR)	7.37 (7.37 - 7.37)			7.31 (7.23 - 7.34)
Min ; Max	7.37 ; 7.37			7.23 ; 7.34
No Crystalloids and Colloids doses given between baseline and time0				
N	1	0	0	3
Mean (SD)	7.37 (NE)			7.29 (0.06)
Median (IQR)	7.37 (7.37 - 7.37)			7.31 (7.23 - 7.34)
Min ; Max	7.37 ; 7.37			7.23 ; 7.34

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	Trauma	Other
Platelets, N (%)		
Baseline		
N	0	0
<50 10^9/L		
>=50 10^9/L		
No Platelets dose given between baseline and time0, N (%)		
N	0	0
<50 10^9/L		
>=50 10^9/L		
pH		
Baseline		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
No Crystalloids and Colloids doses given between baseline and time0		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.
Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony
pH, N (%)				
Baseline				
N	1 (100.0)	0	0	3 (100.0)
<7.2	0			0
>=7.2	1 (100.0)			3 (100.0)
No Crystalloids and Colloids doses given between baseline and time0, N (%)				
N	1 (100.0)	0	0	3 (100.0)
<7.2	0			0
>=7.2	1 (100.0)			3 (100.0)
Body temperature (C)				
Baseline				
N	1	0	0	6
Mean (SD)	36.40 (NE)			36.47 (0.57)
Median (IQR)	36.40 (36.40 - 36.40)			36.50 (36.30 - 37.00)
Min ; Max	36.4 ; 36.4			35.5 ; 37.0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by cause of PPH for patients exposed to NovoSeven® - PS analysis set

	Trauma	Other
pH, N (%)		
Baseline		
N	0	0
<7.2		
>=7.2		
No Crystalloids and Colloids doses given between baseline and time0, N (%)		
N	0	0
<7.2		
>=7.2		
Body temperature (C)		
Baseline		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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14.3.5.5 Baseline laboratory parameters - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony
Number of patients	14	3	0	23
Fibrinogen (g/L)				
Baseline				
N	0.8	1.0	0	1.8
Mean (SD)	1.59 (0.60)	1.50 (NE)		1.92 (0.06)
Median (IQR)	1.05 (1.05 - 2.40)	1.50 (1.50 - 1.50)		1.88 (1.88 - 2.02)
Min ; Max	1.05 ; 2.40	1.50 ; 1.50		1.88 ; 2.02
No Fibrinogen dose given between baseline and time0				
N	0.8	1.0	0	1.8
Mean (SD)	1.59 (0.60)	1.50 (NE)		1.92 (0.06)
Median (IQR)	1.05 (1.05 - 2.40)	1.50 (1.50 - 1.50)		1.88 (1.88 - 2.02)
Min ; Max	1.05 ; 2.40	1.50 ; 1.50		1.88 ; 2.02
Fibrinogen, N (%)				
Baseline				
N	0.8 (100.0)	1.0 (100.0)	0	1.8 (100.0)
<2 g/L	0.5 (60.0)	1.0 (100.0)		1.3 (71.4)
>=2 g/L	0.3 (40.0)	0		0.5 (28.6)
No Fibrinogen dose given between baseline and time0, N (%)				
N	0.8 (100.0)	1.0 (100.0)	0	1.8 (100.0)
<2 g/L	0.5 (60.0)	1.0 (100.0)		1.3 (71.4)
>=2 g/L	0.3 (40.0)	0		0.5 (28.6)

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by cause of PPH for matched controls - PS analysis set

	Trauma	Other
Number of patients	2	1
Fibrinogen (g/L)		
Baseline		
N	0.3	0
Mean (SD)	3.76 (NE)	
Median (IQR)	3.76 (3.76 - 3.76)	
Min ; Max	3.76 ; 3.76	
No Fibrinogen dose given between baseline and time0		
N	0.3	0
Mean (SD)	3.76 (NE)	
Median (IQR)	3.76 (3.76 - 3.76)	
Min ; Max	3.76 ; 3.76	
Fibrinogen, N (%)		
Baseline		
N	0.3 (100.0)	0
<2 g/L	0	
>=2 g/L	0.3 (100.0)	
No Fibrinogen dose given between baseline and time0, N (%)		
N	0.3 (100.0)	0
<2 g/L	0	
>=2 g/L	0.3 (100.0)	

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony
Haemoglobin (g/L)				
Baseline				
N	1.8	1.0	0	3.3
Mean (SD)	73.9 (5.0)	72.0 (NE)		76.6 (7.2)
Median (IQR)	72.0 (66.0 - 76.0)	72.0 (72.0 - 72.0)		75.0 (75.0 - 76.0)
Min ; Max	66 ; 93	72 ; 72		65 ; 97
No RBC units given between baseline and time0				
N	0.5	0	0	1.3
Mean (SD)	75.0 (0.7)			73.2 (4.0)
Median (IQR)	75.0 (74.0 - 76.0)			75.0 (75.0 - 75.0)
Min ; Max	74 ; 76			66 ; 75
Platelets (10 ⁹ /L)				
Baseline				
N	1.3	1.0	0	1.8
Mean (SD)	142.0 (31.4)	51.0 (NE)		113.0 (29.6)
Median (IQR)	108.0 (97.0 - 193.0)	51.0 (51.0 - 51.0)		119.0 (55.0 - 144.0)
Min ; Max	97 ; 198	51 ; 51		55 ; 155
No Platelets dose given between baseline and time0				
N	1.3	0	0	1.8
Mean (SD)	142.0 (31.4)			113.0 (29.6)
Median (IQR)	108.0 (97.0 - 193.0)			119.0 (55.0 - 144.0)
Min ; Max	97 ; 198			55 ; 155

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by cause of PPH for matched controls - PS analysis set

	Trauma	Other
Haemoglobin (g/L)		
Baseline		
N	0.3	0
Mean (SD)	101.0 (NE)	
Median (IQR)	101.0 (101.0 - 101.0)	
Min ; Max	101 ; 101	
No RBC units given between baseline and time0		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Platelets (10 ⁹ /L)		
Baseline		
N	0.3	0
Mean (SD)	223.0 (NE)	
Median (IQR)	223.0 (223.0 - 223.0)	
Min ; Max	223 ; 223	
No Platelets dose given between baseline and time0		
N	0.3	0
Mean (SD)	223.0 (NE)	
Median (IQR)	223.0 (223.0 - 223.0)	
Min ; Max	223 ; 223	

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony
Platelets, N (%)				
Baseline				
N	1.3 (100.0)	1.0 (100.0)	0	1.8 (100.0)
<50 10 ⁹ /L	0	0		0
>=50 10 ⁹ /L	1.3 (100.0)	1.0 (100.0)		1.8 (100.0)
No Platelets dose given between baseline and time0, N (%)				
N	1.3 (100.0)	0	0	1.8 (100.0)
<50 10 ⁹ /L	0			0
>=50 10 ⁹ /L	1.3 (100.0)			1.8 (100.0)
pH				
Baseline				
N	1.5	1.0	0	1.3
Mean (SD)	7.31 (0.04)	7.20 (NE)		7.51 (0.07)
Median (IQR)	7.31 (7.31 - 7.31)	7.20 (7.20 - 7.20)		7.54 (7.54 - 7.54)
Min ; Max	7.21 ; 7.38	7.20 ; 7.20		7.38 ; 7.54
No Crystalloids and Colloids doses given between baseline and time0				
N	1.3	1.0	0	1.3
Mean (SD)	7.32 (0.03)	7.20 (NE)		7.51 (0.07)
Median (IQR)	7.31 (7.31 - 7.31)	7.20 (7.20 - 7.20)		7.54 (7.54 - 7.54)
Min ; Max	7.31 ; 7.38	7.20 ; 7.20		7.38 ; 7.54

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by cause of PPH for matched controls - PS analysis set

	Trauma	Other
Platelets, N (%)		
Baseline		
N	0.3 (100.0)	0
<50 10 ⁹ /L	0	
>=50 10 ⁹ /L	0.3 (100.0)	
No Platelets dose given between baseline and time0, N (%)		
N	0.3 (100.0)	0
<50 10 ⁹ /L	0	
>=50 10 ⁹ /L	0.3 (100.0)	
pH		
Baseline		
N	0.3	0
Mean (SD)	7.40 (NE)	
Median (IQR)	7.40 (7.40 - 7.40)	
Min ; Max	7.40 ; 7.40	
No Crystalloids and Colloids doses given between baseline and time0		
N	0.3	0
Mean (SD)	7.40 (NE)	
Median (IQR)	7.40 (7.40 - 7.40)	
Min ; Max	7.40 ; 7.40	

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by cause of PPH for matched controls - PS analysis set

	AIP	Placental abruption	Placental retention	Uterine atony
pH, N (%)				
Baseline				
N	1.5 (100.0)	1.0 (100.0)	0	1.3 (100.0)
<7.2	0	0		0
>=7.2	1.5 (100.0)	1.0 (100.0)		1.3 (100.0)
No Crystalloids and Colloids doses given between baseline and time0, N (%)				
N	1.3 (100.0)	1.0 (100.0)	0	1.3 (100.0)
<7.2	0	0		0
>=7.2	1.3 (100.0)	1.0 (100.0)		1.3 (100.0)
Body temperature (C)				
Baseline				
N	2.1	1.3	0	2.3
Mean (SD)	36.88 (0.38)	36.66 (0.76)		36.63 (0.31)
Median (IQR)	36.70 (36.40 - 37.40)	37.00 (37.00 - 37.00)		37.00 (36.30 - 37.00)
Min ; Max	36.2 ; 37.4	35.3 ; 37.0		36.0 ; 37.0

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by cause of PPH for matched controls - PS analysis set

	Trauma	Other
pH, N (%)		
Baseline		
N	0.3 (100.0)	0
<7.2	0	
>=7.2	0.3 (100.0)	
No Crystalloids and Colloids doses given between baseline and time0, N (%)		
N	0.3 (100.0)	0
<7.2	0	
>=7.2	0.3 (100.0)	
Body temperature (C)		
Baseline		
N	0.3	0
Mean (SD)	36.10 (NE)	
Median (IQR)	36.10 (36.10 - 36.10)	
Min ; Max	36.1 ; 36.1	

PPH: Postpartum haemorrhage, PS: Propensity score, AIP: Abnormally invasive placenta (including praevia), N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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14.3.5.6 Baseline laboratory parameters - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® -PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
Number of patients	2	0	15
Fibrinogen (g/L)			
Baseline			
N	0	0	7
Mean (SD)			1.94 (0.68)
Median (IQR)			2.15 (1.31 - 2.26)
Min ; Max			1.25 ; 3.09
No Fibrinogen dose given between baseline and time0			
N	0	0	6
Mean (SD)			1.90 (0.74)
Median (IQR)			1.74 (1.31 - 2.26)
Min ; Max			1.25 ; 3.09
Fibrinogen, N (%)			
Baseline			
N	0	0	7 (100.0)
<2 g/L			3 (42.9)
>=2 g/L			4 (57.1)
No Fibrinogen dose given between baseline and time0, N (%)			
N	0	0	6 (100.0)
<2 g/L			3 (50.0)
>=2 g/L			3 (50.0)

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), RBC: Red blood cells.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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Baseline laboratory parameters - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® -PS analysis set

	After first invasive procedure	Missing
1.0 Number of patients	1	0
Fibrinogen (g/L)		
Baseline		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
No Fibrinogen dose given between baseline and time0		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Fibrinogen, N (%)		
Baseline		
N	0	0
<2 g/L		
>=2 g/L		
No Fibrinogen dose given between baseline and time0, N (%)		
N	0	0
<2 g/L		
>=2 g/L		

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), RBC: Red blood cells.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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Baseline laboratory parameters - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® -PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
Haemoglobin (g/L)			
Baseline			
N	0	0	8
Mean (SD)			82.5 (23.7)
Median (IQR)			84.5 (64.5 - 95.5)
Min ; Max			49 ; 122
No RBC units given between baseline and time0			
N	0	0	2
Mean (SD)			69.0 (18.4)
Median (IQR)			69.0 (56.0 - 82.0)
Min ; Max			56 ; 82
Platelets (10 ⁹ /L)			
Baseline			
N	0	0	5
Mean (SD)			205.0 (260.9)
Median (IQR)			103.0 (86.0 - 122.0)
Min ; Max			45 ; 669
No Platelets dose given between baseline and time0			
N	0	0	4
Mean (SD)			234.8 (291.3)
Median (IQR)			112.5 (74.0 - 395.5)
Min ; Max			45 ; 669

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), RBC: Red blood cells.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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Baseline laboratory parameters - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® -PS analysis set

	After first invasive procedure	Missing
Haemoglobin (g/L)		
Baseline		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
No RBC units given between baseline and time0		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
Platelets (10^9/L)		
Baseline		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
No Platelets dose given between baseline and time0		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), RBC: Red blood cells.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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Baseline laboratory parameters - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® -PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
Platelets, N (%)			
Baseline			
N	0	0	5 (100.0)
<50 10 ⁹ /L			1 (20.0)
>=50 10 ⁹ /L			4 (80.0)
No Platelets dose given between baseline and time0, N (%)			
N	0	0	4 (100.0)
<50 10 ⁹ /L			1 (25.0)
>=50 10 ⁹ /L			3 (75.0)
pH			
Baseline			
N	0	0	4
Mean (SD)			7.31 (0.06)
Median (IQR)			7.32 (7.27 - 7.35)
Min ; Max			7.23 ; 7.37
No Crystalloids and Colloids doses given between baseline and time0			
N	0	0	4
Mean (SD)			7.31 (0.06)
Median (IQR)			7.32 (7.27 - 7.35)
Min ; Max			7.23 ; 7.37

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), RBC: Red blood cells.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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Baseline laboratory parameters - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® -PS analysis set

	After first invasive procedure	Missing
Platelets, N (%)		
Baseline		
N	0	0
<50 10 ⁹ /L		
>=50 10 ⁹ /L		
No Platelets dose given between baseline and time0, N (%)		
N	0	0
<50 10 ⁹ /L		
>=50 10 ⁹ /L		
pH		
Baseline		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		
No Crystalloids and Colloids doses given between baseline and time0		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), RBC: Red blood cells.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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Baseline laboratory parameters - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® -PS analysis set

	Without any invasive procedure	Before first invasive procedure	During operation with an invasive procedure
pH, N (%)			
Baseline			
N	0	0	4 (100.0)
<7.2			0
>=7.2			4 (100.0)
No Crystalloids and Colloids doses given between baseline and time0, N (%)			
N	0	0	4 (100.0)
<7.2			0
>=7.2			4 (100.0)
Body temperature (C)			
Baseline			
N	0	0	7
Mean (SD)			36.46 (0.52)
Median (IQR)			36.40 (36.30 - 37.00)
Min ; Max			35.5 ; 37.0

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), RBC: Red blood cells.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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Baseline laboratory parameters - by timing of first NovoSeven® dose from invasive procedure for patients exposed to NovoSeven® -PS analysis set

	After first invasive procedure	Missing
pH, N (%)		
Baseline		
N	0	0
<7.2		
>=7.2		
No Crystalloids and Colloids doses given between baseline and time0, N (%)		
N	0	0
<7.2		
>=7.2		
Body temperature (C)		
Baseline		
N	0	0
Mean (SD)		
Median (IQR)		
Min ; Max		

PS: Propensity score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), RBC: Red blood cells.

Without any invasive procedure: Women that do not have any invasive procedure during the study period. Before first invasive procedure: First dose of NovoSeven® occurs before the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered before that operation starts. During operation with an invasive procedure: First dose of NovoSeven® and the first invasive procedure occurs during the same operation. After first invasive procedure: First dose of NovoSeven® occurs after the first invasive procedure, if the invasive procedure occurs during an operation, then NovoSeven® is administered after that operation ends. The five categories are mutually exclusive and together cover all cases.

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14.3.5.7 Baseline laboratory parameters - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Number of patients	4	14
Fibrinogen (g/L)		
Baseline		
N	2	5
Mean (SD)	2.17 (1.30)	1.85 (0.49)
Median (IQR)	2.17 (1.25 - 3.09)	2.15 (1.33 - 2.22)
Min ; Max	1.25 ; 3.09	1.31 ; 2.26
No Fibrinogen dose given between baseline and time0		
N	2	4
Mean (SD)	2.17 (1.30)	1.76 (0.51)
Median (IQR)	2.17 (1.25 - 3.09)	1.74 (1.32 - 2.21)
Min ; Max	1.25 ; 3.09	1.31 ; 2.26
Fibrinogen, N (%)		
Baseline		
N	2 (100.0)	5 (100.0)
<2 g/L	1 (50.0)	2 (40.0)
>=2 g/L	1 (50.0)	3 (60.0)
No Fibrinogen dose given between baseline and time0, N (%)		
N	2 (100.0)	4 (100.0)
<2 g/L	1 (50.0)	2 (50.0)
>=2 g/L	1 (50.0)	2 (50.0)

sPPH: Severe postpartum haemorrhage, PS: Propensity Score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Haemoglobin (g/L)		
Baseline		
N	2	6
Mean (SD)	79.5 (33.2)	83.5 (23.7)
Median (IQR)	79.5 (56.0 - 103.0)	84.5 (73.0 - 88.0)
Min ; Max	56 ; 103	49 ; 122
No RBC units given between baseline and time0		
N	1	1
Mean (SD)	56.0 (NE)	82.0 (NE)
Median (IQR)	56.0 (56.0 - 56.0)	82.0 (82.0 - 82.0)
Min ; Max	56 ; 56	82 ; 82
Platelets (10^9/L)		
Baseline		
N	1	4
Mean (SD)	122.0 (NE)	225.8 (296.5)
Median (IQR)	122.0 (122.0 - 122.0)	94.5 (65.5 - 386.0)
Min ; Max	122 ; 122	45 ; 669
No Platelets dose given between baseline and time0		
N	1	3
Mean (SD)	122.0 (NE)	272.3 (344.7)
Median (IQR)	122.0 (122.0 - 122.0)	103.0 (45.0 - 669.0)
Min ; Max	122 ; 122	45 ; 669

sPPH: Severe postpartum haemorrhage, PS: Propensity Score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.
Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.
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Baseline laboratory parameters - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
Platelets, N (%)		
Baseline		
N	1 (100.0)	4 (100.0)
<50 10 ⁹ /L	0	1 (25.0)
>=50 10 ⁹ /L	1 (100.0)	3 (75.0)
No Platelets dose given between baseline and time0, N (%)		
N	1 (100.0)	3 (100.0)
<50 10 ⁹ /L	0	1 (33.3)
>=50 10 ⁹ /L	1 (100.0)	2 (66.7)
pH		
Baseline		
N	0	4
Mean (SD)		7.31 (0.06)
Median (IQR)		7.32 (7.27 - 7.35)
Min ; Max		7.23 ; 7.37
No Crystalloids and Colloids doses given between baseline and time0		
N	0	4
Mean (SD)		7.31 (0.06)
Median (IQR)		7.32 (7.27 - 7.35)
Min ; Max		7.23 ; 7.37

sPPH: Severe postpartum haemorrhage, PS: Propensity Score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by first NovoSeven® administration time from onset of sPPH for patients exposed to NovoSeven® - PS analysis set

	< 30 minutes after onset of sPPH	>= 30 minutes after onset of sPPH
pH, N (%)		
Baseline		
N	0	4 (100.0)
<7.2		0
>=7.2		4 (100.0)
No Crystalloids and Colloids doses given between baseline and time0, N (%)		
N	0	4 (100.0)
<7.2		0
>=7.2		4 (100.0)
Body temperature (C)		
Baseline		
N	0	7
Mean (SD)		36.46 (0.52)
Median (IQR)		36.40 (36.30 - 37.00)
Min ; Max		35.5 ; 37.0

sPPH: Severe postpartum haemorrhage, PS: Propensity Score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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14.3.5.8 Baseline laboratory parameters - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Number of patients	2	16	0
Fibrinogen (g/L)			
Baseline			
N	1	6	0
Mean (SD)	1.25 (NE)	2.06 (0.67)	
Median (IQR)	1.25 (1.25 - 1.25)	2.19 (1.33 - 2.26)	
Min ; Max	1.25 ; 1.25	1.31 ; 3.09	
No Fibrinogen dose given between baseline and time0			
N	1	5	0
Mean (SD)	1.25 (NE)	2.03 (0.74)	
Median (IQR)	1.25 (1.25 - 1.25)	2.15 (1.33 - 2.26)	
Min ; Max	1.25 ; 1.25	1.31 ; 3.09	
Fibrinogen, N (%)			
Baseline			
N	1 (100.0)	6 (100.0)	0
<2 g/L	1 (100.0)	2 (33.3)	
>=2 g/L	0	4 (66.7)	
No Fibrinogen dose given between baseline and time0, N (%)			
N	1 (100.0)	5 (100.0)	0
<2 g/L	1 (100.0)	2 (40.0)	
>=2 g/L	0	3 (60.0)	

PS: Propensity Score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Haemoglobin (g/L)			
Baseline			
N	1	7	0
Mean (SD)	56.0 (NE)	86.3 (22.9)	
Median (IQR)	56.0 (56.0 - 56.0)	87.0 (73.0 - 103.0)	
Min ; Max	56 ; 56	49 ; 122	
No RBC units given between baseline and time0			
N	1	1	0
Mean (SD)	56.0 (NE)	82.0 (NE)	
Median (IQR)	56.0 (56.0 - 56.0)	82.0 (82.0 - 82.0)	
Min ; Max	56 ; 56	82 ; 82	
Platelets (10 ⁹ /L)			
Baseline			
N	1	4	0
Mean (SD)	122.0 (NE)	225.8 (296.5)	
Median (IQR)	122.0 (122.0 - 122.0)	94.5 (65.5 - 386.0)	
Min ; Max	122 ; 122	45 ; 669	
No Platelets dose given between baseline and time0			
N	1	3	0
Mean (SD)	122.0 (NE)	272.3 (344.7)	
Median (IQR)	122.0 (122.0 - 122.0)	103.0 (45.0 - 669.0)	
Min ; Max	122 ; 122	45 ; 669	

PS: Propensity Score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
Platelets, N (%)			
Baseline			
N	1 (100.0)	4 (100.0)	0
<50 10 ⁹ /L	0	1 (25.0)	
>=50 10 ⁹ /L	1 (100.0)	3 (75.0)	
No Platelets dose given between baseline and time0, N (%)			
N	1 (100.0)	3 (100.0)	0
<50 10 ⁹ /L	0	1 (33.3)	
>=50 10 ⁹ /L	1 (100.0)	2 (66.7)	
pH			
Baseline			
N	0	4	0
Mean (SD)		7.31 (0.06)	
Median (IQR)		7.32 (7.27 - 7.35)	
Min ; Max		7.23 ; 7.37	
No Crystalloids and Colloids doses given between baseline and time0			
N	0	4	0
Mean (SD)		7.31 (0.06)	
Median (IQR)		7.32 (7.27 - 7.35)	
Min ; Max		7.23 ; 7.37	

PS: Propensity Score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by first dose of NovoSeven® (µg/kg) for patients exposed to NovoSeven® - PS analysis set

	<60 µg/kg	60-90 µg/kg	>90 µg/kg
pH, N (%)			
Baseline			
N	0	4 (100.0)	0
<7.2		0	
>=7.2		4 (100.0)	
No Crystalloids and Colloids doses given between baseline and time0, N (%)			
N	0	4 (100.0)	0
<7.2		0	
>=7.2		4 (100.0)	
Body temperature (C)			
Baseline			
N	0	7	0
Mean (SD)		36.46 (0.52)	
Median (IQR)		36.40 (36.30 - 37.00)	
Min ; Max		35.5 ; 37.0	

PS: Propensity Score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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14.3.5.9 Baseline laboratory parameters - by gestational age for patients exposed to NovoSeven®- PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	2	11	5	0
Fibrinogen (g/L)				
Baseline				
N	0	5	2	0
Mean (SD)		2.03 (0.76)	1.73 (0.59)	
Median (IQR)		2.22 (1.33 - 2.26)	1.73 (1.31 - 2.15)	
Min ; Max		1.25 ; 3.09	1.31 ; 2.15	
No Fibrinogen dose given between baseline and time0				
N	0	4	2	0
Mean (SD)		1.98 (0.87)	1.73 (0.59)	
Median (IQR)		1.80 (1.29 - 2.68)	1.73 (1.31 - 2.15)	
Min ; Max		1.25 ; 3.09	1.31 ; 2.15	
Fibrinogen, N (%)				
Baseline				
N	0	5 (100.0)	2 (100.0)	0
<2 g/L		2 (40.0)	1 (50.0)	
>=2 g/L		3 (60.0)	1 (50.0)	
No Fibrinogen dose given between baseline and time0, N (%)				
N	0	4 (100.0)	2 (100.0)	0
<2 g/L		2 (50.0)	1 (50.0)	
>=2 g/L		2 (50.0)	1 (50.0)	

PS: Propensity Score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by gestational age for patients exposed to NovoSeven®- PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Haemoglobin (g/L)				
Baseline				
N	0	6	2	0
Mean (SD)		83.2 (27.7)	80.5 (10.6)	
Median (IQR)		84.5 (56.0 - 103.0)	80.5 (73.0 - 88.0)	
Min ; Max		49 ; 122	73 ; 88	
No RBC units given between baseline and time0				
N	0	2	0	0
Mean (SD)		69.0 (18.4)		
Median (IQR)		69.0 (56.0 - 82.0)		
Min ; Max		56 ; 82		
Platelets (10 ⁹ /L)				
Baseline				
N	0	3	2	0
Mean (SD)		278.7 (340.2)	94.5 (12.0)	
Median (IQR)		122.0 (45.0 - 669.0)	94.5 (86.0 - 103.0)	
Min ; Max		45 ; 669	86 ; 103	
No Platelets dose given between baseline and time0				
N	0	3	1	0
Mean (SD)		278.7 (340.2)	103.0 (NE)	
Median (IQR)		122.0 (45.0 - 669.0)	103.0 (103.0 - 103.0)	
Min ; Max		45 ; 669	103 ; 103	

PS: Propensity Score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by gestational age for patients exposed to NovoSeven®- PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Platelets, N (%)				
Baseline				
N	0	3 (100.0)	2 (100.0)	0
<50 10 ⁹ /L		1 (33.3)	0	
>=50 10 ⁹ /L		2 (66.7)	2 (100.0)	
No Platelets dose given between baseline and time0, N (%)				
N	0	3 (100.0)	1 (100.0)	0
<50 10 ⁹ /L		1 (33.3)	0	
>=50 10 ⁹ /L		2 (66.7)	1 (100.0)	
pH				
Baseline				
N	0	2	2	0
Mean (SD)		7.35 (0.02)	7.27 (0.06)	
Median (IQR)		7.35 (7.34 - 7.37)	7.27 (7.23 - 7.31)	
Min ; Max		7.34 ; 7.37	7.23 ; 7.31	
No Crystalloids and Colloids doses given between baseline and time0				
N	0	2	2	0
Mean (SD)		7.35 (0.02)	7.27 (0.06)	
Median (IQR)		7.35 (7.34 - 7.37)	7.27 (7.23 - 7.31)	
Min ; Max		7.34 ; 7.37	7.23 ; 7.31	

PS: Propensity Score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by gestational age for patients exposed to NovoSeven®- PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
pH, N (%)				
Baseline				
N	0	2 (100.0)	2 (100.0)	0
<7.2		0	0	
>=7.2		2 (100.0)	2 (100.0)	
No Crystalloids and Colloids doses given between baseline and time0, N (%)				
N	0	2 (100.0)	2 (100.0)	0
<7.2		0	0	
>=7.2		2 (100.0)	2 (100.0)	
Body temperature (C)				
Baseline				
N	0	4	3	0
Mean (SD)		36.30 (0.62)	36.67 (0.35)	
Median (IQR)		36.35 (35.90 - 36.70)	36.70 (36.30 - 37.00)	
Min ; Max		35.5 ; 37.0	36.3 ; 37.0	

PS: Propensity Score, N: Number of patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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14.3.5.10 Baseline laboratory parameters - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Number of patients	1	26	16	0
Fibrinogen (g/L)				
Baseline				
N	0	1.4	2.5	0
Mean (SD)		2.15 (0.71)	1.76 (0.24)	
Median (IQR)		1.89 (1.05 - 2.40)	1.88 (1.50 - 1.88)	
Min ; Max		1.05 ; 3.76	1.50 ; 2.02	
No Fibrinogen dose given between baseline and time0				
N	0	1.4	2.5	0
Mean (SD)		2.15 (0.71)	1.76 (0.24)	
Median (IQR)		1.89 (1.05 - 2.40)	1.88 (1.50 - 1.88)	
Min ; Max		1.05 ; 3.76	1.50 ; 2.02	
Fibrinogen, N (%)				
Baseline				
N	0	1.4 (100.0)	2.5 (100.0)	0
<2 g/L		0.8 (52.9)	2.0 (80.0)	
>=2 g/L		0.7 (47.1)	0.5 (20.0)	
No Fibrinogen dose given between baseline and time0, N (%)				
N	0	1.4 (100.0)	2.5 (100.0)	0
<2 g/L		0.8 (52.9)	2.0 (80.0)	
>=2 g/L		0.7 (47.1)	0.5 (20.0)	

PS: Propensity Score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Haemoglobin (g/L)				
Baseline				
N	0.3	2.4	3.8	0
Mean (SD)	93.0 (NE)	75.4 (6.5)	75.9 (7.7)	
Median (IQR)	93.0 (93.0 - 93.0)	72.0 (66.0 - 76.0)	75.0 (72.0 - 75.0)	
Min ; Max	93 ; 93	66 ; 101	65 ; 97	
No RBC units given between baseline and time0				
N	0	0.8	1.0	0
Mean (SD)		72.0 (2.6)	75.0 (NE)	
Median (IQR)		74.0 (66.0 - 76.0)	75.0 (75.0 - 75.0)	
Min ; Max		66 ; 76	75 ; 75	
Platelets (10 ⁹ /L)				
Baseline				
N	0.3	1.4	2.8	0
Mean (SD)	108.0 (NE)	167.1 (36.3)	90.5 (35.6)	
Median (IQR)	108.0 (108.0 - 108.0)	193.0 (97.0 - 198.0)	55.0 (51.0 - 144.0)	
Min ; Max	108 ; 108	97 ; 223	51 ; 155	
No Platelets dose given between baseline and time0				
N	0.3	1.4	1.8	0
Mean (SD)	108.0 (NE)	167.1 (36.3)	113.0 (29.6)	
Median (IQR)	108.0 (108.0 - 108.0)	193.0 (97.0 - 198.0)	119.0 (55.0 - 144.0)	
Min ; Max	108 ; 108	97 ; 223	55 ; 155	

PS: Propensity Score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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Baseline laboratory parameters - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
Platelets, N (%)				
Baseline				
N	0.3 (100.0)	1.4 (100.0)	2.8 (100.0)	0
<50 10 ⁹ /L	0	0	0	
>=50 10 ⁹ /L	0.3 (100.0)	1.4 (100.0)	2.8 (100.0)	
No Platelets dose given between baseline and time0, N (%)				
N	0.3 (100.0)	1.4 (100.0)	1.8 (100.0)	0
<50 10 ⁹ /L	0	0	0	
>=50 10 ⁹ /L	0.3 (100.0)	1.4 (100.0)	1.8 (100.0)	
pH				
Baseline				
N	0.3	1.8	2.0	0
Mean (SD)	7.21 (NE)	7.34 (0.03)	7.37 (0.24)	
Median (IQR)	7.21 (7.21 - 7.21)	7.31 (7.31 - 7.38)	7.37 (7.20 - 7.54)	
Min ; Max	7.21 ; 7.21	7.31 ; 7.40	7.20 ; 7.54	
No Crystalloids and Colloids doses given between baseline and time0				
N	0	1.8	2.0	0
Mean (SD)		7.34 (0.03)	7.37 (0.24)	
Median (IQR)		7.31 (7.31 - 7.38)	7.37 (7.20 - 7.54)	
Min ; Max		7.31 ; 7.40	7.20 ; 7.54	

PS: Propensity Score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

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NovoSeven®
Trial ID: NN7711-4729

Non-interventional report
Report body

Date:
Version:

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1.0

Status:
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Novo Nordisk

Baseline laboratory parameters - by gestational age for matched controls - PS analysis set

	<28 weeks	28-37 weeks	>37 weeks	Missing
pH, N (%)				
Baseline				
N	0.3 (100.0)	1.8 (100.0)	2.0 (100.0)	0
<7.2	0	0	0	
>=7.2	0.3 (100.0)	1.8 (100.0)	2.0 (100.0)	
No Crystalloids and Colloids doses given between baseline and time0, N (%)				
N	0	1.8 (100.0)	2.0 (100.0)	0
<7.2		0	0	
>=7.2		1.8 (100.0)	2.0 (100.0)	
Body temperature (C)				
Baseline				
N	0	3.2	2.8	0
Mean (SD)		36.62 (0.41)	36.78 (0.35)	
Median (IQR)		36.55 (36.10 - 37.40)	37.00 (36.30 - 37.00)	
Min ; Max		35.3 ; 37.4	36.0 ; 37.0	

PS: Propensity Score, N: Number of (weighted) patients, %: Percentage of patients, SD: Standard deviation, IQR: Inter-quartile range (25th percentile - 75th percentile), NE: Not Estimable, RBC: Red blood cells.

Baseline laboratory parameter values are the closest values to time0 within a time frame of 60 minutes before time0.

/fvii/nn7711-4729/ctr_20210821_er
18AUG2021:14:44:15 - tsumlbbase.sas/tsumlbbasegagagectrlpsas.txt

15 References

1. Public Policy Committee. International Society of Pharmacoepidemiology. Guidelines for good pharmacoepidemiology practice (GPP). *Pharmacoepidemiol Drug Saf.* 2016;25(1):2-10.
2. Colucci G, Helsing K, Biasiutti FD, Raio L, Schmid P, Tsakiris DA, et al. Standardized Management Protocol in Severe Postpartum Hemorrhage: A Single-Center Study. *Clin Appl Thromb Hemost.* 2018;24(6):884-93.
3. Ashigbie P. Update on 2004 Background Paper, BP 6.16 Postpartum Haemorrhage. 2013.
4. Edwards HM. Aetiology and treatment of severe postpartum haemorrhage. *Dan Med J.* 2018;65(3).
5. Zhang Y, Yan J, Han Q, Yang T, Cai L, Fu Y, et al. Emergency obstetric hysterectomy for life-threatening postpartum hemorrhage: A 12-year review. *Medicine (Baltimore).* 2017;96(45):e8443.
6. Kallianidis AF, Maraschini A, Danis J, Colmorn LB, Deneux-Tharaux C, Donati S, et al. Epidemiological analysis of peripartum hysterectomy across nine European countries. *Acta Obstet Gynecol Scand.* 2020;99(10):1364-73.
7. Magon N, Babu KM, Kapur K, Chopra S, Joneja GS. Recombinant activated factor VII in post partum haemorrhage. *Niger Med J.* 2013;54(5):289-94.
8. Muñoz M, Stensballe J, Ducloy-Bouthors AS, Bonnet MP, De Robertis E, Fornet I, et al. Patient blood management in obstetrics: prevention and treatment of postpartum haemorrhage. A NATA consensus statement. *Blood Transfus.* 2019;17(2):112-36.
9. Say L, Chou D, Gemmill A, Tunçalp Ö, Moller AB, Daniels J, et al. Global causes of maternal death: a WHO systematic analysis. *Lancet Glob Health.* 2014;2(6):e323-33.
10. Prevention and Management of Postpartum Haemorrhage: Green-top Guideline No. 52. *BJOG.* 2017;124(5):e106-e49.
11. Girard T, Mörtl M, Schlembach D. New approaches to obstetric hemorrhage: the postpartum hemorrhage consensus algorithm. *Curr Opin Anaesthesiol.* 2014;27(3):267-74.
12. Novo Nordisk A/S. NovoSeven® (eptacog alfa (activated)), EU Summary of product characteristics (SmPC). 09 Nov 2020.
13. Magon N, Babu K. Recombinant Factor VIIa in Post-partum Hemorrhage: A New Weapon in Obstetrician's Armamentarium. *N Am J Med Sci.* 2012;4(4):157-62.
14. Lavigne-Lissalde G, Aya AG, Mercier FJ, Roger-Christoph S, Chauleur C, Morau E, et al. Recombinant human FVIIa for reducing the need for invasive second-line therapies in severe refractory postpartum hemorrhage: a multicenter, randomized, open controlled trial. *J Thromb Haemost.* 2015;13(4):520-9.
15. Abdul Sultan A, Grainge MJ, West J, Fleming KM, Nelson-Piercy C, Tata LJ. Impact of risk factors on the timing of first postpartum venous thromboembolism: a population-based cohort study from England. *Blood.* 2014;124(18):2872-80.
16. Chauleur C, Cochery-Nouvellon E, Mercier E, Aya G, Marès P, Mismetti P, et al. Analysis of the venous thromboembolic risk associated with severe postpartum haemorrhage in the NOHA First cohort. *Thromb Haemost.* 2008;100(5):773-9.
17. Abbasi N, Balayla J, Laporta DP, Kezouh A, Abenhaim HA. Trends, risk factors and mortality among women with venous thromboembolism during labour and delivery: a population-based study of 8 million births. *Arch Gynecol Obstet.* 2014;289(2):275-84.
18. Zhou ZH, Chen Y, Zhao BH, Jiang Y, Luo Q. Early Postpartum Venous Thromboembolism: Risk Factors and Predictive Index. *Clin Appl Thromb Hemost.* 2019;25:1076029618818777.
19. Bouma LS, Bolte AC, van Geijn HP. Use of recombinant activated factor VII in massive postpartum haemorrhage. *Eur J Obstet Gynecol Reprod Biol.* 2008;137(2):172-7.

20. Franchini M, Franchi M, Bergamini V, Montagnana M, Salvagno GL, Targher G, et al. The use of recombinant activated FVII in postpartum hemorrhage. Clin Obstet Gynecol. 2010;53(1):219-27.
21. Schmid P, Mordasini A, Luginbühl M, Regli B, Kohler HP, Zimmermann H, et al. Low-dose recombinant factor VIIa for massive bleeding: a single centre observational cohort study with 73 patients. Swiss Med Wkly. 2011;141:w13213.
22. Schlembach D, Helmer H, Henrich W, von Heymann C, Kainer F, Korte W, et al. Peripartum Haemorrhage, Diagnosis and Therapy. Guideline of the DGGG, OEGGG and SGGG (S2k Level, AWMF Registry No. 015/063, March 2016). Geburtshilfe Frauenheilkd. 2018;78(4):382-99.
23. European Medicines Agency. Guideline on registry-based studies (EMA/502388/2020). 24 September 2020.
24. Fernandez-Bello I, Stenmo C, Butta N, Lind V, Ezban M, Jimenez-Yuste V. Assessment of *in vivo* administered recombinant activated factor VII by thrombelastography using two different coagulation activators. PO-EHF09. 23–26 June 2014. International Society on Thrombosis and Haemostasis (ISTH) Scientific and Standardization Committee Annual Meeting; Milwaukee, Wisconsin, US.
25. Austin PC. An introduction to propensity score methods for reducing the effects of confounding in observational studies. Multivariate Behav Res. 2011;46(3):399-424.
26. Lu B. Propensity score matching with time-dependent covariates. Biometrics. 2005;61(3):721-8.

Appendices

Annex 1. List of stand-alone documents

Number	Document reference number	Date	Title
1	16.1.1	01 September 2021	Protocol and protocol amendments
2	16.1.2	01 September 2021	Sample data collection sheet
3	16.1.3	01 September 2021	List of Independent Ethics Committees and/or Institutional Review Boards
4	16.1.4	01 September 2021	List and description of physicians in the study
5	16.1.5	02 September 2021	Signatures of signatory physicians and sponsor
6	16.1.7	01 September 2021	Documentation of statistical methods
7	16.1.9	01 September 2021	Publications based on the study <i>Not applicable</i>
8	16.1.10	01 September 2021	Important publications referenced in the report <i>Available upon request</i>

Annex 2. Additional information

Number	Document reference number	Date	Title
1	16.2.3	01 September 2021	Patients excluded from efficacy analysis
2	16.2.6	01 September 2021	Individual efficacy response data
3	16.2.7	01 September 2021	Adverse event listings
4	16.2.9	01 September 2021	Standalone documents