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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Study Finalised

Administrative details

EU PAS number

EUPAS35429

Study ID

44949

DARWIN EU® study

No

Study countries

☐ Switzerland

Study description

This non-interventional study will compare the clinical outcomes in women with an event of severe postpartum haemorrhage treated with NovoSeven® to clinical outcomes in women with an event of severe postpartum haemorrhage not treated with NovoSeven®. The study will be a single centre retrospective cohort study of women with an event of severe postpartum haemorrhage, defined as 1.5 L of blood loss within 24 hours of delivery, in the period of 2005-2016.

Study status

Finalised

Research institutions and networks

Institutions

Novo Nordisk

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Institution

Contact details

Study institution contact

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Actual: 20/05/2020

Study start date

Planned: 22/06/2020

Actual: 29/06/2020

Date of final study report

Planned: 13/01/2022

Actual: 02/09/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk A/S

Study protocol

4729-protocol-eu-pas-reg-redacted.pdf (1.25 MB)

_ Public Registration of Results 4729-protocol-ver-3-eu-pas-reg-redacted.pdf (1.1 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

WHO UTN: U1111-1248-2816

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To compare the incidence of invasive procedures in women with an event of severe PostPartum Haemorrhage (sPPH) treated with NovoSeven® to the incidence of invasive procedures in women with an event of sPPH but not treated with NovoSeven®. Invasive procedures are defined as: uterine or iliac artery ligation, radiological arterial embolisation, uterine compression sutures, or hysterectomy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Postpartum haemorrhage

Population studied

Short description of the study population

Women with severe postpartum haemorrhage (sPPH) who were treated with NovoSeven® or other standard of care, respectively including data from four cohorts of sPPH patients during the period of January 2006-April 2016.

Inclusion criteria

For an eligible patient, all inclusion criteria must be answered “yes”.

1. Females

2. sPPH, defined as continuous bleeding of more than 1500 mL within 24 hours after delivery

3. Inclusion in one of the four cohorts (historical cohort 1, historical cohort 2, study cohort and new cohort)

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

225

Study design details

Outcomes

Occurrence of invasive procedures (yes/no) 20 min-24 hours following time0. Exposed women:Time0 is defined as time of first administration of NovoSeven®. It occurs x minutes after onset of sPPH. Matched controls:Time0 is derived from the matching process. It is equal to the period from onset of sPPH to time of first administration of NovoSeven® for the patient for which

they are a matched control. Occurrence of thromboembolic events (yes/no) from time0 until 5 days after time0. Amount of blood products transfused from delivery to 24h after time0 Estimated blood loss from delivery to 24h after time0 Occurrence of hysterectomy (yes/no) 20min-24hours following time0 (Time0 definition - see under primary outcomes.)

Data analysis plan

The primary objective will be answered using propensity score matching to ensure exchangeability between sPPH patient treated with NovoSeven® and those that are not across all 4 cohorts (if these are comparable). These analyses will be addressed using data from the patient`s electronic record that includes timing of variables. To answer the secondary objectives, the comparisons will be made using the matched women from the propensity score matching described above. A significance level (alpha) of 0.05 will be used.

Documents

Study results

4729 ctr eu-pas-reg redacted.pdf (7.26 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Data originates from original database collected by Colucci et al. These data were analysed together with the supplemental data from women in the new cohort collected retrospectively from electronic medical records. Furthermore, for women included in the study published by Colucci et al, additional information on timing of different interventions will be collected.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No