PASS TachoSil Evaluation (PasTel): Short- and long-term safety evaluation of TachoSil in paediatric population

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000505

Study ID

1000000505

DARWIN EU® study

No

Study countries

Poland

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Piotr Czauderna

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/08/2024

Study start date

Planned: 31/07/2026

Actual: 30/07/2026

Date of final study report

Planned: 31/03/2031

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

PasTel_Study_Protocol_en_V2.2_final__2025_10_30.pdf (961.85 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

This is a prospective, multicentre, non-interventional, uncontrolled, observational, post authorisation cohort study.

Main study objective:

PRIMARY OBJECTIVES

1. To evaluate the occurrence of clinically significant local reactions at the site of TachoSil application, as detected through routine imaging (X-ray, ultrasound, CT, MRI) or intraoperative detection or physical examination.

SECONDARY OBJECTIVES

1. To determine the occurrence of tissue adhesions, as detected through routine imaging (X-ray, ultrasound, CT, MRI) or intraoperative detection or physical examination.
2. To determine the occurrence of AESIs reported during the perioperative period, including:

■ Thrombotic and embolic events. Postoperative bleeding at surgical site and at the site of application of
the investigational medicinal product.

■ Allergic reactions / Immediate hypersensitivity reactions.

■ Other surgical related infections at the site of application of the investigational medicinal product.

3. To determine the occurrence of adverse events related to the use of the study product in the period from the start of surgery up to 36 months post-surgery.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

TACHOSIL

Study drug International non-proprietary name (INN) or common name

HUMAN THROMBIN

HUMAN FIBRINOGEN

Anatomical Therapeutic Chemical (ATC) code

(B02BC30) combinations

combinations

Population studied

Short description of the study population

The study population is paediatric patients undergoing a cardiovascular, hepatic or other solid organs surgery and polytrauma with injuries of blood vessels, parenchymal organs, lungs requiring the use of drugs for local haemostasis, tissue sealing when control of bleeding by standard surgical techniques (such as suture, ligature, clips or cautery) appeared to be ineffective or impractical.

Infants and toddlers (>= 28 days - < 2 years) on the day of signing the ICF
Children (>=2 years – < 12 years) on the day of signing the ICF
Adolescents (>=12 years – less than 15 years) on the day of signing the ICF

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Study design details

Setting

The study will include approx. 4 sites or more, if required

Outcomes

Primary endpoint:

1. The proportion of subjects experiencing clinically significant local reactions including abscesses, hematoma formation or foreign body granuloma formulation, at the site of TachoSil application from the start of surgery up to 36 months post-surgery, as detected through routine imaging examinations (X-ray, ultrasound, CT, MRI or intraoperative detection or physical examination).

Secondary endpoints:

1.The proportion of subjects experiencing clinically significant tissue adhesions detected from the start of surgery up to 36 months post-surgery, as detected through routine imaging tests such as X-ray, ultrasound, computed tomography, magnetic resonance imaging or relaparotomy or intraoperative detection or physical examination.

2.Proportion of subjects experiencing at least one AESI during the perioperative period (from start of surgery until hospital discharge):

• Thrombotic and embolic events

• Postoperative bleeding at surgical site and at the site of application of the investigational medicinal product

• Allergic reactions / Immediate hypersensitivity reactions

• Other surgical related infections at the site of application of the investigational medicinal product

3.Proportion of subjects experiencing at least one AE related to the use of the study product in the period from the start of surgery up to 36 months post-surgery.

Data analysis plan

All analyses will be performed for the study population, which will comprise all enrolled subjects who received at least 1 application of TachoSil. Study endpoints will be summarised by descriptive statistics. For primary and secondary endpoints, rate of occurrence and cumulative incidence of AEs and AESIs will be determined. Time to onset (TTO), duration, severity, outcome, treatment and relatedness to TachoSil will be analyzed for reported AEs and AESI. Descriptive statistics of all endpoints may include specifically but not exclusively, arithmetic mean, medians, standard deviations, proportions, frequency counts and 25th and 75th percentiles. Where applicable, 95% confidence intervals of select point estimates will be determined. Figures will be prepared to illustrate the patterns of data over time where appropriate. The number of subjects included in each analysis set will be reported. A qualitative comparison of results collected during the study with an existing literature data will be performed, particularly focusing on the incidences, time to onset, severity, and outcomes of AESIs and SAEs, with existing literature. Literature searches in databases like PubMed, Embase and Cochrane Library will be conducted to identify relevant studies. The search will use specific keywords and criteria related to TachoSil, adverse events, and study populations. Studies selected for comparison will be based on relevance, quality, and up to date results. Key data from the selected studies, such as incidences, time to onset, severity, and outcomes of AESIs and SAEs, will be extracted. A standardized form will be used to ensure consistent data collection. A narrative synthesis will be provided, discussing similarities and differences in the findings. Both our study and the selected literature will undergo a critical appraisal to assess the quality and risk of bias, which will be considered in the interpretation of the results.

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)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

No

Check completeness

No

Check stability

No

Check logical consistency

No

Data characterisation

Data characterisation conducted

No