

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

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Study

Planned

Administrative details

EU PAS number

EUPAS1000000505

Study ID

1000000505

DARWIN EU® study

No

Study countries

☐ Poland

Study status

Planned

Contact details

Study institution contact

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Study contact

mirosław.kociecki@corza.com

Primary lead investigator

Piotr Kalicinski

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/08/2024

Study start date

Planned: 31/12/2024

Date of final study report

Planned: 30/06/2029

Sources of funding

- Pharmaceutical company and other private sector

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

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

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)

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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