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

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000505

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

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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

Name of medicine

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

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