

Safety and effectiveness of Pradaxa oral pellet formulation for treatment of acute venous thromboembolic events (VTE) and/or for risk reduction of recurrence of VTE in pediatric patients aged 3 months to less than 12 years in a real world setting: a prospective non-interventional study conducted in the United States

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Study

Discontinued

Administrative details

EU PAS number

EUPAS1000000981

Study ID

1000000981

DARWIN EU® study

No

Study countries

 United States

Study description

The main research question of this study is to obtain further safety and effectiveness data on Pradaxa Pellets in children aged 3 months to less than 12 years in routine clinical practice setting.

Study status

Discontinued

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator
Boehringer Ingelheim

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 12/11/2021

Study start date

Actual: 19/04/2024

Date of final study report

Actual: 06/11/2025

Study protocol

[Protocol_and_Protocol_Amendment_04_Feb_2026__Redacted.pdf](#) (539.99 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

1160-0309

NCT05966740

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)

Study drug and medical condition

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

DABIGATRAN ETEXILATE

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

Additional medical condition(s)

Venous Thromboembolism

Population studied

Short description of the study population

Pediatric patients aged 3 months to less than 12 years, who may be considered for anticoagulation with Pradaxa Pellets due to venous thromboembolic events (VTE), are usually treated in neonatology, pediatric general surgery, cardiac surgery or intensive care units. Pediatric patients with anticoagulation with Pradaxa Pellets for the prevention of recurrent VTE are usually evaluated by pediatric hematologists in pediatric hematology units. Any of these patients that are prescribed Pradaxa pellets may be considered for inclusion into this study.

Age groups

- **Paediatric Population (< 18 years)**

- Neonate
 - Preterm newborn infants (0 – 27 days)
 - Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Study design details

Outcomes

Primary Outcome:

- Cumulative incidence of clinically relevant bleeding events

Secondary Outcomes:

- Occurrence of recurrent Venous Thromboembolic Event (VTE)
- Mortality related to thrombotic or thromboembolic events
- Occurrence of all bleeding events
- Occurrence of post-thrombotic syndrome (PTS)
- Incidence of adverse events (AEs)
- Incidence of serious adverse events (SAEs)
- Thrombotic burden at the end of the treatment period vs baseline, i.e. image-based resolution status of the thrombus (complete response, partial response, stable disease, progressive disease)
- Recurrence of VTE while on treatment
- Duration of treatment with dabigatran etexilate
- Compliance with dabigatran etexilate treatment

Documents

Study results

[1160-0309_Synopsis.pdf](#) (220.96 KB)

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

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown