

# Safety of dabigatran etexilate (DE) for treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from birth to less than 2 years of age: a prospective European non-interventional cohort study based on new data collection (1160.307)

**First published:** 29/06/2022

**Last updated:** 22/09/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS47909

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### Study ID

47910

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### DARWIN EU® study

No

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## Study countries

-  Austria
  -  Czechia
  -  Denmark
  -  Finland
  -  Germany
  -  Italy
  -  Netherlands
  -  Spain
  -  Sweden
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## Study status

Finalised

## Research institutions and networks

### Institutions

C.H. van Ommen

## Contact details

### Study institution contact

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**Study contact**

[c.vanommen@erasmusmc.nl](mailto:c.vanommen@erasmusmc.nl)

### Primary lead investigator

C.H. van Ommen

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual: 24/12/2021

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### **Study start date**

Planned: 15/12/2022

Actual: 10/08/2022

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### **Date of final study report**

Planned: 20/06/2025

Actual: 25/11/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim International GmbH

## Study protocol

[1160.307\\_NIS-protocol\\_v.3.0\\_signed\\_redacted.pdf](#) (452.52 KB)

## Regulatory

## Was the study required by a regulatory body?

Yes

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## 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

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Safety study (incl. comparative)

#### **Data collection methods:**

Combined primary data collection and secondary use of data

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#### **Study design:**

This is a prospective, non-interventional, European, multinational, multi-center cohort study based on newly collected data of pediatric patients anticoagulated with DE for acute VTE treatment or prevention of recurrent VTE.

**Main study objective:**

The objective of this study was to evaluate the safety of DE for the treatment of VTE and prevention of recurrent VTE in children from birth to < 2 years of age in a routine clinical practice setting.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

PRADAXA

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

DABIGATRAN ETEXILATE

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**Anatomical Therapeutic Chemical (ATC) code**

(B01AE07) dabigatran etexilate

dabigatran etexilate

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**Medical condition to be studied**

Embolism venous

## Population studied

## **Age groups**

- Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
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## **Estimated number of subjects**

50

# Study design details

## **Outcomes**

- The incidence of any bleeding events defined as Major Bleeding Events (MBE) or Non- Major Bleeding Events (Non-MBE).
  - Incidence of AEs.
  - Incidence of SAEs (see Sections 11.1 and 11.2).
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## **Data analysis plan**

Safety outcomes from this single-arm study will be interpreted in the context of findings from the paediatric developmental program, i. e. acute VTE treatment (DIVERSITY) and secondary VTE prevention studies.

As this is a descriptive non-interventional study, no hypotheses will be tested, rather, all variables will be presented using descriptive statistics (absolute and relative frequencies, means, standard deviations, medians, ranges, minimum and maximum values, 95% confidence intervals CI and incidences as appropriate for the nature of the variables (i.e. categorical or continuous)).

Safety outcomes will be summarized as incidence with 95% CIs using Wilson method. All AE/ verbatim terms will be recorded and coded using the Medical Dictionary for Regulatory Activities (MedDRA).

Concomitant medications will be recorded according to World Health

### **Summary results**

The objective of this PASS which was to evaluate the safety of DE for the treatment of VTE and prevention of recurrent VTE in children from birth to < 2 years of age in a routine clinical practice setting could not be accomplished for feasibility reasons.

The availability of alternative paediatric treatments on the market, current clinical practices, investigator preferences, and the non-availability of the DE OS formulation collectively presented significant obstacles.

Given these challenges, any future attempt to conduct a similar study is highly likely to encounter similar feasibility issues.

## Documents

### **Study report**

[1160.307 Observational and Non-Interventional Study \(ONIS\)](#)

[Report\\_ABSTRACT\\_Redacted.pdf](#) (273.68 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.

## Data sources

## **Data sources (types)**

Other

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### **Data sources (types), other**

Prospective patient-based data collection

## **Use of a Common Data Model (CDM)**

### **CDM mapping**

No

## **Data quality specifications**

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## **Data characterisation**

### **Data characterisation conducted**

No