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: 30/10/2024

Study Planned

Administrative details

EU PAS number

EUPAS47909

Study ID

47910

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Czechia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Poland
- [ ] Spain
- [ ] Sweden

Study status

Planned

Research institutions and networks

Institutions

C.H. van Ommen

Contact details

Study institution contact

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Study contact

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Primary lead investigator

C.H. van Ommen

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 24/12/2021

Study start date
Planned: 15/12/2022

Date of final study report
Planned: 20/06/2025

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

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:

Combined primary data collection and secondary use of data

Main study objective:

The objective of this study is 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

Name of medicine

PRADAXA

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

DABIGATRAN ETEXILATE

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

Medical condition to be studied

Embolism venous

Population studied

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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).

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 Organisation Drug Dictionary (WHO-DD).

Data management

Data sources

Data sources (types)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No