Xarelto Paediatric VTE PASS Drug Utilization Study: An observational, longitudinal, multi-source drug utilization safety study to evaluate the drug use patterns and safety of rivaroxaban oral suspension in children under two years with venous thromboembolism (XAPAEDUS)

First published: 10/05/2023

Last updated: 04/12/2025

Study Planned

Administrative details

EU PAS number

EUPAS46800

Study ID

104927

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] France
- [ ] Spain
- [ ] Sweden

Study description

This is an observational study in which only data are collected from participants receiving their usual treatment. The study is done in children under 2 years old with venous thromboembolism (VTE). VTE is a condition in which blood clots form in the veins, usually in the leg. This can cause pain and swelling. The clot can also break apart and travel in the blood to the lungs where it can block the blood flow. This can be life threatening.

Rivaroxaban is approved for doctors to prescribe to children with VTE, but there is limited information about how it is used, how well it works, and how safe it is in children under 2 years old. Children in this study are already receiving or will receive rivaroxaban or other currently used medicines for VTE from their doctor according to the approved product information. The purpose of this study is to collect information on the pattern of use and safety of rivaroxaban and other standard medicines for VTE in children under 2 years old.

The main information that researchers will collect in this study: Age, gender, and other information about the child and their illness. Type of VTE treatment given to the child.

Occurrence of medically important bleeding and its severity. Further information that researchers will collect: Changes in the characteristics of the children given VTE treatment (e.g. changes in the age range of children given VTE treatment) and changes in the treatment pattern for VTE. Return of VTE symptoms. Types of doctors who prescribe VTE treatment and their set-up (e.g. special clinics versus hospitals). Besides this data collection, no further tests or examinations are needed in this study.

The data for this study will be collected from electronic health records and health insurance claims data until 2026. Researchers will observe each child during treatment until the child has a bleeding episode, VTE symptoms return, VTE treatment ends, or death, their information is no longer available, or the study ends.

Study status

Planned

Research institutions and networks

Institutions

Bayer AG

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

Contact details

Study institution contact

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Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials Contact BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/12/2022

Study start date
Planned: 01/09/2026

Date of final study report
Planned: 28/02/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

22195_Study Protocol_Redacted_V2.1_2022-11-16.pdf (735.21 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

- Clinical characteristics and demographics of patients when using anticoagulation therapy for the treatment of VTE (rivaroxaban oral suspension or SOC)
- Use of anticoagulation therapy (including selected drug, dose, and duration) for treatment of VTE
- Incidence and severity of bleeding (major bleeding, and clinically relevant non-major bleeding) according to anticoagulation therapy

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

RIVAROXABAN

Anatomical Therapeutic Chemical (ATC) code

(B01AF01) rivaroxaban

rivaroxaban

Medical condition to be studied

Embolism venous

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)

Estimated number of subjects

850

Study design details

Outcomes

- Demographic characteristics of patients - Characteristics of index VTE - Co-morbidities reported in the previous six months before index date, or since date of birth for children less than six months
- Major bleeding according to anticoagulation therapy
- Clinically Relevant Non-Major (CRNM) bleeding according to anticoagulation therapy Please see more in protocol, - Time trends by calendar year in patient characteristics
- Time trends by calendar year in anticoagulation treatment patterns
- Incidence of recurrent symptomatic VTE according to anticoagulation therapy
- Physician specialty and care settings (inpatient care, secondary outpatient care, primary care) for prescriptions of anticoagulation therapy

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Data analysis plan

Given the study objectives the analyses will be descriptive, with no intent for hypothesis generating or testing between exposure categories. Incidences in Rivaroxaban and SOC cohorts will be compared only in an exploratory sense and no confirmatory statistical tests will be performed. All analyses will be conducted separately by country and data source. Besides, combined analyses

of aggregated data across data sources will be provided, as applicable. Categorical variables will be presented as counts (n), and proportions (%), with 95% CI where relevant. Continuous variables will be presented as means with standard deviation and as medians with interquartile range, where appropriate.

Documents

Study report

22195__Progress report1_Redacted_V1.0_2023-10-31.pdf (191.38 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 source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

The Information System for Research in Primary Care (SIDIAP)

Data source(s), other

Système National Des Données De Santé (SNDS) France, Danish Register of Medicinal Products Statistics (RMPS) Denmark, Danish Hospital Patient

Medication Register (SMR) Denmark, Swedish National Patient Register (NPR) Sweden, Swedish Cause of Death Register Sweden

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

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