An observational post-authorization Modified Prescription-Event Monitoring safety study to monitor the safety and utilization of rivaroxaban (XARELTO®) for the prevention of stroke in patients with AF, treatment of DVT and PE, and prevention of recurrent DVT and PE following an acute DVT in the primary care setting in England, extended to include Acute Coronary Syndrome Patients (Rivaroxaban MPEM)

First published: 25/10/2016

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS15961

Study ID

28575

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Rivaroxaban is a highly selective direct factor Xa inhibitor which inhibits thrombin formation and the development of thrombi. This M-PEM study will enable the systematic collection and reporting of drug utilisation and safety data on patients newly initiated on treatment with rivaroxaban in the primary care setting. The study aims to collect exposure and outcome data for a cohort of approximately 10,000 evaluable patients.

Study status

Finalised

Research institutions and networks

Institutions

Drug Safety Research Unit (DSRU)

United Kingdom

First published: 10/11/2021

Last updated: 09/01/2026

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

Elizabeth Lynn elizabeth.lynn@dsru.org

Study contact

elizabeth.lynn@dsru.org

Primary lead investigator

Saad Shakir

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/01/2012

Actual: 19/01/2012

Study start date

Planned: 01/12/2011

Actual: 31/01/2012

Data analysis start date

Planned: 01/06/2017

Actual: 01/06/2017

Date of interim report, if expected

Planned: 29/11/2013

Actual: 03/12/2013

Date of final study report
Planned: 28/02/2018

Actual: 27/10/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer

Study protocol

Rivaroxaban_M_PEM_ Full_Protocol_FINAL_ACS_extension_16_04_2015.pdf (1.55 MB)

Rivaroxaban_M_PEM_ Full_Protocol_FINAL_PASS_v6_17_04_2015.pdf (1.46 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Estimation of the cumulative incident risk (separately) of the following important identified risk for rivaroxaban users which is:• Haemorrhage within gastrointestinal and urogenital organ sites (which meets the criteria for a major bleed) and all intracranial sites.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

XARELTO

Population studied

Short description of the study population

Patients prescribed rivaroxaban in the primary care setting in England.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

10.000

Study design details

Outcomes

The incidence risk of:(a) all major bleeding specified in primary objective for rivaroxaban (as composite)(b) (separately) haemorrhage within critical organ sites other than specified in primary objective for rivaroxaban(d) all major and clinically relevant non-major bleeds (as a composite outcome)(e) thromboembolic complications (incident and recurrent)

Data analysis plan

PEM methodology provides a numerator (the number of reports of an event) and a denominator (the number of patient-months at risk), both collected within a known time frame. This allows for the calculation of risk (percent of total valid cohort exposed) and incidence densities (ID, person-time incidence rates) for each event. Such analyses will be performed using ‘Higher-level’ event terms from the MedDRA dictionary.

Documents

Study results

DSRU MPEM EUPAS15961 - Abstract Final Results_uploaded to encepp.pdf

(134.43 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

Data sources (types), other

Prescription event monitoring

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