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

PURI

https://redirect.ema.europa.eu/resource/28575

EU PAS number

EUPAS15961

Study ID

28575

DARWIN EU® study

No

Study countries

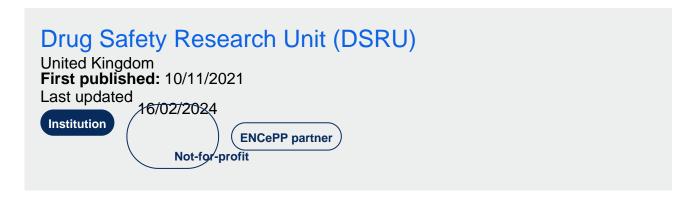United Kingdom

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 institution and networks

Institutions

Drug Safety Research Unit (DSRU)
United Kingdom
First published: 10/11/2021
Last updated 16/02/2024

Institution   Not-for-profit   ENCePP partner

Contact details

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Primary lead investigator
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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

Name of medicine
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
10000

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

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