An Observational Post-Authorization Safety Specialist Cohort Event Monitoring Study (SCEM) to Monitor the Safety and Utilization of Rivaroxaban (Xarelto®) for the Prevention of Stroke in Patients with AF, Treatment of DVT and PE, and the Prevention of Recurrent DVT and PE in the Secondary Care Hospital Setting in England and Wales (ROSE)

First published: 22/05/2013

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS3979

Study ID

28398

DARWIN EU® study

No

Study countries

United Kingdom

Study description

A study to evaluate the use and short term safety of Rivaroxaban (Xarelto®) during real-life use in Secondary Care (hospitals) in England and Wales. Rivaroxaban is an anti-coagulant medication which has previously been used only in patients having hip or knee replacement surgery but will now also be used to prevent stroke and systemic embolism in patients with non-valvular atrial fibrillation. Rivaroxaban will also be used to treat deep vein thrombosis (DVT) and pulmonary embolism (PE) and to prevent recurrent DVT and PE. This study aims to evaluate the use of rivaroxaban and its short term safety when used by patients for these new indications. This study was requested by the Committee for Medicinal products for Human use (CHMP). The study will recruit patients starting rivaroxaban treatment and asking their care team to answer some simple questions about them at the time they start and again in 12 weeks time. The study will also recruit patients starting alternative anticoagulant therapies and their care team will be asked the same questions. These patients will be used to compare the differences between users of rivaroxaban and users of alternative anticoagulant therapies. If a participant has an adverse event during the 12 week period, we may ask the patient’s care team to fill out a further follow up questionnaire. No other examinations or tests will be performed. The participant’s consent will be obtained to access their medical charts. Any adult patient started by their care team on rivaroxaban or an alternative anticoagulant for the specified indications during the study period will be eligible to take part. It is a national study covering the whole of England and Wales. The study will last for approximately 3 years of data collection (in

order to reach a cohort of 3400 patients - 1700 rivaroxaban users and 1700 alternative anticoagulant therapy users), although each individual patient will only be involved for a 12 week period of observation.

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

Networks

Stroke Research Network, Non-malignant Haematology Group, Cardiovascular Group

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Saad Shakir

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/12/2012

Actual: 19/12/2012

Study start date

Planned: 21/05/2013

Actual: 05/09/2013

Data analysis start date

Planned: 01/11/2016

Actual: 31/03/2017

Date of interim report, if expected

Planned: 13/04/2015

Actual: 13/08/2015

Date of final study report

Planned: 28/02/2017

Actual: 26/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer plc

Study protocol

ROSE protocol_v40_20_11_2014.pdf (1.25 MB)

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:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

To monitor the short-term (up to 12 weeks) safety profile and drug utilisation of rivaroxaban as prescribed to patients for medical conditions requiring anticoagulation by specialist Healthcare Professionals in the secondary care hospital setting in England and Wales.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Intensive monitoring schemes

Study drug and medical condition

Medicinal product name

XARELTO

Medical condition to be studied

Atrial fibrillation

Deep vein thrombosis

Pulmonary embolism

Population studied

Short description of the study population

Rivaroxaban prescribed newuser adult patients (i.e. rivaroxaban naïve who may or may not be antithrombotic therapy naïve) for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation, the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and the prevention of recurrent DVT and PE in adult patients, requiring anticoagulation under normal conditions of use in the secondary care hospital setting.

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

3.400

Study design details

Outcomes

To provide timely information for rivaroxaban users on the estimation of the cumulative in 1.Prescriber/cohort accrual, type of prescriber, setting 2.Non-clinical reasons for prescribing, prognostic health factors, clinical risk factors for haemorrhage 3.Changes of health profile/adherence/treatment 4.Quantify risk of haemorrhage within GI/urogenital/intracranial sites for contextual cohort & within critical organ sites for both cohorts, major & non-major bleeds, other events.

Data analysis plan

Data analysis will include • Response rates to describe recruitment • Hazard rates to explore the incidence of selected events • Descriptive analyses of baseline health profile of patients • Analysis of risk and incidence densities to describe the risk profile of events reported in patient subgroups of special interest

Documents

Study results

EU-PAS_Abstract.pdf (458.46 KB)

Study report

CSR 16171 R-11983_EUPAS.pdf (6.13 MB)

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

Unknown