An Observational Post-authorization Safety Specialist Cohort Event Monitoring Study (SCEM) to Monitor the Safety and Utilization of rivaroxaban (XARELTO®) initiated in secondary care for the prevention of atherothrombotic events in patients who have had acute coronary syndrome in England and Wales (ROSE ACS)

First published: 31/07/2015

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS9977

Study ID

35313

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Rivaroxaban is a medicine which reduces the formation of blood clots. Acute coronary syndrome (ACS) comprises a range of disorders, including heart attack and unstable angina, caused by a sudden reduction in blood flow to part of the heart muscle. This study aims to collect information on the use of rivaroxaban and its safety when used by patients for the prevention of artherothrombotic (plaque rupture leading to a blood clot) events following ACS, during the first three months after starting. This study was requested by the European regulatory body (EMA) which is responsible for the use and safety of medicines. It will last for approximately 3 years and is a national study covering the whole of England and Wales. The study aims to recruit 1193 patients who have been prescribed rivaroxaban and antiplatelet therapy and 1193 patients who have been prescribed alternative dual antiplatelet therapy for the secondary prevention of artherothrombotic events following ACS. Each patient will only be monitored for the first 13 weeks after hospital admission for ACS. Patients who choose to take part will complete a consent form. The patient’s care team will be asked to complete a baseline questionnaire about the patient at the time the medicine is given and a further questionnaire up to 16 weeks later, specifically asking about the patient’s experiences whilst on the medication. If anything unusual is reported during the observation period, the care team may be asked to fill out a followup questionnaire. With the patient’s consent, the study team will also inform the patient’s GP of their participation in the study and will ask the GP to complete an abridged questionnaire from the patient’s medical records. The study team will analyse and aggregate the data, carefully

protecting patient confidentiality, to classify adverse events of interest, in particular bleeding events.

Study status

Finalised

Research institutions 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**

Networks

NIHR Medicines for Children Research Network

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

Saad Shakir saad.shakir@dsru.org

Study contact

saad.shakir@dsru.org

Primary lead investigator

Saad Shakir

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/06/2014

Actual: 02/06/2015

Study start date

Planned: 01/09/2015

Actual: 01/09/2015

Date of interim report, if expected

Planned: 30/09/2017

Actual: 27/10/2017

Date of final study report

Planned: 31/10/2019

Actual: 30/10/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer Pharma AG

Study protocol

ACS SCEM Final_30_08_2017_version 7_Clean.pdf(846.95 KB)

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:

Secondary use of data

Main study objective:

1. To quantify the cumulative incidence (risk and rate) of haemorrhage (major bleeding within intracranial, gastrointestinal and urogenital organ sites) occurring in the 12 week observation period

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

RIVAROXABAN

Population studied

Short description of the study population

Patients in the secondary care hospital setting in England and Wales.
This study will be a prospective observational, population-based cohort study of rivaroxaban with a contextual comparator (reference cohort). The rivaroxaban cohort consists of new rivaroxaban users (no anticoagulant prescription within 6 months prior to index date) with any combination of oral antiplatelet therapy for the prevention of atherothrombotic events following ACS. The contextual cohort consists of patients receiving the current standard treatment of care for the prevention of atherothrombotic events following an ACS (at least dual antiplatelet therapy, but not monotherapy).

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

2386

Study design details

Outcomes

Intracranial, gastrointestinal or urogenital major bleeding.

Data analysis plan

- quantify the cumulative incidence (risk and rate) of major bleeding - descriptive exploratory analysis of patient population prescribed rivaroxaban- quantify the risk of other major (in any other site not specified in the primary

objective) or minor bleeding outcomes (in any site) reported in the 12 week observation period overall

Documents

Study results

17542_EU PAS Abstract_Redacted_V1.0_2019-11-21.pdf(296.37 KB)

DSRU SCEM ACS - Abstract Final Report.pdf(125.94 KB)

Study report

17542_Clinical Study Report_Redacted_V1.0_2019-11-21.pdf(8.37 MB)

DSRU EUPAS9977 - Summary Interim Report_3Feb2019.pdf(86.12 KB)

Study, other information

DSRU EUPAS9977 - Summary Interim Report_3Feb2019.pdf(86.12 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Study questionnaires will be completed using data from patient medical records.

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