A pharmacoepidemiological study of Rivaroxaban use and potential adverse outcomes in routine clinical pratice in the United Kingdom

First published: 14/10/2015

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/43192

EU PAS number

EUPAS11299

Study ID

43192

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This prospective cohort study will provide information about: Characteristics of Rivaroxaban use in patients who are prescribed Rivaroxaban for the first time compared to patients who are prescribed standard of care for the first time. The occurrence of intracranial haemorrhage, gastrointestinal and urogenital bleeding, and the occurrence of non-infective liver disease.

Study status

Finalised

Research institutions and networks

Institutions

Fundación Centro Español de Investigación Farmacoepidemiológica (CEIFE)

Spain

First published: 15/03/2010

Last updated: 15/02/2024

Institution **Not-for-profit** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Luis Alberto García Rodríguez

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/01/2012

Study start date

Actual: 22/12/2011

Date of final study report

Planned: 15/11/2020

Actual: 26/11/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer HealthCare AG

Study protocol

16647_THIN_Rivaroxaban protocol.pdf(797.48 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:

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

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To assess patterns of drug utilization and to quantify outcomes related to safety and effectiveness in new users of rivaroxaban compared with new users of standard of care in routine clinical practice in the UK.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

XARELTO

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

RIVAROXABAN

Anatomical Therapeutic Chemical (ATC) code

(B01A) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

Medical condition to be studied

Venous thrombosis

Pulmonary embolism

Atrial fibrillation

Acute coronary syndrome

Population studied

Short description of the study population

All patients aged 2 years and above who have been enrolled in The Health Improvement Network (THIN) database for at least 1 year and had their first prescription recorded in the database at least 1 year ago will be included.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

20000

Study design details

Outcomes

1. Descriptive analysis of demographic and clinical characteristics of patients who are prescribed oral rivaroxaban for the first time in comparison with those who are prescribed standard of care for the first time 2. Characteristics of rivaroxaban use in comparison with standard of care (NOTE: please refer to https://clinicaltrials.gov/ for description of further primary outcomes), 1. Safety:

occurrence of bleeding events leading to hospitalization not specified as primary safety outcomes ("other bleeding") in individuals receiving rivaroxaban, in comparison with those receiving current standard of care. (NOTE: please refer to https://clinicaltrials.gov/ for description of further secondary outcomes)

Data analysis plan

For descriptive purposes, annualized crude incidence rates of the specified outcome Events will be calculated, accompanied by 95% confidence intervals.

Documents

Study results

Combined Report_16159_16646_16647_17543_EU PAS Abstract_Redacted_V1.0_2020-11-26.pdf(152.16 KB)

Study report

16647_Progress report_v1.0._2019-01-28.pdf(93.11 KB)

Xarelto PASS - Combined Report_16159_16646_16647_17543_redacted_final.pdf(592.92 KB)

Study, other information

Xarelto PASS - Combined Report_16159_16646_16647_17543_redacted_final.pdf(592.92 KB)

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Data sources (types)

Drug dispensing/prescription data

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