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 institution 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 data collection

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

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