A pharmacoepidemiological study of rivaroxaban use and potential adverse outcomes in routine clinical practice in Sweden

First published: 09/06/2015

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS9895

Study ID

43212

DARWIN EU® study

No

Study countries

☐ Sweden

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

Friberg Research AB, Karolinska Institute

Sweden

First published: 19/03/2014

Last updated: 20/08/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Laboratory/Research/Testing facility

Contact details

Study institution contact

Leif Friberg leif.friberg@ki.se

Study contact

leif.friberg@ki.se

Primary lead investigator

Leif Friberg

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/02/2015

Actual: 10/02/2015

Study start date

Planned: 01/06/2015

Actual: 15/06/2015

Date of final study report

Actual: 26/11/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer Pharma AG

Study protocol

Sweden_Rivaroxaban protocol_EMA PASS template_20150120_clean_final.pdf
(246.56 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 Sweden.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

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

Acute coronary syndrome

Venous thrombosis

Pulmonary embolism

Atrial fibrillation

Population studied

Short description of the study population

All patients who have filled a prescription for rivaroxaban, warfarin, aspirin, clopidogrel, ticlopidine, prasugrel or ticagrelor in any pharmacy in Sweden.

Age groups

- Infants and toddlers (28 days – 23 months)
- 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)

Special population of interest

Renal impaired

Estimated number of subjects

40000

Study design details

Outcomes

1) Descriptive analysis of demographic and clinical characteristics of patients who are prescribed oral rivaroxaban for the first time 2) Occurrence of hospitalization for a) intracranial haemorrhage, (b) gastrointestinal bleeding, (c) urogenital bleeding among users of rivaroxaban, 1) Occurrence of hospitalization for bleeding events not specified as primary safety outcomes 2) Occurrence of non-infective liver disease 3) Outcomes related to effectiveness (ischaemic stroke or myocardial infarction) 4) All-cause mortality as well as cause-specific mortality

---

Data analysis plan

The diagnosis associated with the prescribing of the index drug will be grouped by indication. The patient populations will be described according to demographics, previous and current disease and concomitant medication at baseline both overall and stratified by indication. For descriptive purposes, annualized crude incidence rates of the specified outcome events will be calculated, accompanied by 95% confidence intervals. For evaluation of safety and effectiveness outcome events, Cox proportional hazards regression model will be used. Propensity score matching will be done to account for confounding by indication.

Documents

Study results

EUPAS9895-43209.pdf (152.16 KB)

Study report

EUPAS9895-43210.pdf (592.92 KB)

Sweden EUPAS9895 - Summary Interim Report.pdf (92.61 KB)

Sweden EUPAS9895_ Progress report.pdf (15.21 KB)

Study, other information

Sweden EUPAS9895_ Progress report.pdf (15.21 KB)

Sweden EUPAS9895 - Summary Interim Report.pdf (92.61 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

National Swedish Drug Register Sweden, National Swedish Patient Register Sweden, National Cause of Death Register Sweden, Swedish LISA (Longitudinal integration database for health insurance and labour market studies) database

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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