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

First published: 09/06/2015
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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/43212

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 institution and networks

Institutions

Friberg Research AB, Karolinska Institute

Sweden
First published: 19/03/2014
Last updated
26/03/2014

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

Contact details

Study institution contact
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Study contact

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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 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 Sweden.

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
100000093931
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

Data sources

Data source(s)
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 data (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