A pharmacoepidemiological study of Rivaroxaban use and potential adverse outcomes in routine clinical pratice in Germany

First published: 01/10/2015

Last updated: 08/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11145

Study ID

43353

DARWIN EU® study

No

Study countries

☐ Germany

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

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

Last updated: 26/02/2024

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Tania Schink

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 06/08/2012

Study start date

Actual: 22/12/2011

Date of final study report

Planned: 31/10/2020

Actual: 01/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer HealthCare AG

Study protocol

16159_GePaRD_Rivaroxaban protocol.pdf(601.88 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 Germany.

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 German Pharmcoepidemiological Research Database (GePaRD) for at least 1 year. Cohorts of first-time users of either rivaroxaban or comparators will be identified using the date of first dispensation of the respective drug (the index drug) as the index date.

A patient will be considered eligible to enter a study cohort as a first-time user of rivaroxaban or a first-time user of “standard of care” when he or she has a first prescription of the drug dispensed during the enrolment period. In Germany, for VTE prevention, DVT/PE treatment and SPAF, standard of care is treatment with the most widely used vitamin K antagonist, phenprocoumon, and for the secondary prevention of ACS, standard of care is antiplatelet drug(s) such as low-dose acetylsalicylic acid, clopidogrel, dipyridamole, prasugrel, ticlopidine and ticagrelor. Many patients with ACS have a history of ischaemic heart disease for which platelet inhibition is standard treatment, and thus exclusion of patients with prior use of platelet inhibitors risks excluding a majority of typical ACS patients. Therefore, those who have been using one or more platelet inhibitors will remain eligible to enter the study.

Patients who have any record of being dispensed their index drug in the year before index date (i.e. cohort entry), or who qualify for both cohorts on the same day will be excluded. If a patient qualifies as first-time user of both rivaroxaban and “standard of care” comparison drug during the enrolment period, she/he will be assigned to the cohort of drug first prescribed during the enrolment period, with the date of this prescription being the index date. Many patients with ACS have a history of ischaemic heart disease for which platelet inhibition is standard treatment, and thus exclusion of patients with prior use of platelet inhibitors risks excluding a majority of typical ACS patients. Therefore, those who have been using one or more plate

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)

Special population of interest

Other

Special population of interest, other

Patients with venous thrombosis, pulmonary embolism, atrial fibrillation, acute coronary syndrome

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Estimated number of subjects

200000

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 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 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

Abstract_FinalReport.pdf(346.53 KB)

Study report

16159_Progress report_v1.0_2019-01-28.pdf(94.9 KB)

PASS_report_Germany_1Dec2020.pdf(8 MB)

Study, other information

PASS_report_Germany_1Dec2020.pdf(8 MB)

Study publications

Jobski K, Enders D, Amann U, Suzart K, Wallander MA, Schink T, Garbe E. Use of ...

Data management

Data sources

Data source(s)

German Pharmacoepidemiological Research Database

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Discharge registry, death registry, cancer registry, and registries holding socio-demographic 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