Real-world comparative effectiveness of stroke prevention in patients with atrial fibrillation treated with rivaroxaban vs. vitamin k antagonists (RELOAD)

First published: 12/10/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS15755

Study ID

28914

DARWIN EU® study

No

Study countries

Germany

Study description

The aim of this study is to assess the real world comparative effectiveness of Rivaroxaban prescribed in non-valvular atrial fibrillation (NVAF) routine care patients in Germany.

Study status

Finalised

Research institutions and networks

Institutions

Germany

Contact details

Study institution contact

Bayer Clinical Trials Contact BAYER AG clinical-trials-contact@bayer.com

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials Contact BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 28/04/2016

Actual: 28/04/2016

Study start date
Planned: 15/10/2016

Actual: 15/10/2016

Date of final study report
Planned: 28/02/2017

Actual: 06/10/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

18735_PRC_OS_Secondary Data_SPAF_v2_final_with signatures_2016-10-27.pdf
(3 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

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

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The main objective of this study is to assess the riskof ischemic stroke (effectiveness) and intracranialhemorrhage (ICH, safety) in patients treated withRivaroxaban compared to patients treated with Phenprocoumon

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AA04) phenprocoumon

phenprocoumon

(B01AF01) rivaroxaban

rivaroxaban

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Patients, newly initiated with Rivaroxaban or Phenprocoumon with an non-valvular atrial fibrillation (NVAF) diagnosis from January 1, 2012 through December 31, 2015.

Age groups

- 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

Atrial fibrillation patients

Estimated number of subjects

99.999

Study design details

Outcomes

- Risk of ischemic stroke - Risk of intracranial hemorrhage (ICH), - Risk of ischemic stroke or ICH- Risk of systemic embolism (SE)- Risk of transient ischemic attack (TIA)- Risk of ischemic stroke or SE or TIA For more details please visit www.clinicaltrials.gov

Data analysis plan

Time-to-event analyses using unadjusted and adjusted multivariate cox proportional hazard models and a 1:1 propensity score matched analyses will be conducted to estimate Hazard Ratios and corresponding confidence intervals.

Documents

Study results

18735_EUPAS_Abstract.pdf (67.96 KB)

Study report

18735_Reload_Report 2.0final_06102017_redacted.pdf (2.86 MB)

Data management

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 sources (types)

Administrative healthcare records (e.g., claims)

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

Unknown