Evaluation of Clinical outcomes among non-valvular atrial fibrillatIon patients with renal dysfunction treated with warfarin or reduced dose rivaroxaban (CALLIPER)

First published: 28/11/2017

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Study | Finalised

Administrative details

EU PAS number

EUPAS21253

Study ID

32656

DARWIN EU® study

No

Study countries

Germany

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Bayer Clinical Trials BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/11/2017

Actual: 08/11/2017

Study start date
Planned: 01/12/2017

Actual: 01/12/2017

Date of final study report
Planned: 13/09/2019

Actual: 05/09/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

OS_Protocol_RenalDysfunction_MarketScan_v5.pdf (297.71 KB)

19721_Study Protocol_V2.0_Redacted.pdf (885.39 KB)

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 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 objective of the study is to evaluate the effectiveness and safety of the reduced dose rivaroxaban (15mg once daily) as compared to warfarin in non-valvular atrial fibrillation (NVAF) patients with renal dysfunction in routine clinical practice. The study has a retrospective design, and will be conducted in the US Truven Health MarketScan Commercial Claims and Medicare Supplemental Databases.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

RIVAROXABAN

Anatomical Therapeutic Chemical (ATC) code

(B01AA03) warfarin

warfarin

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

All the insured individuals included in the Truven Health MarketScan databases. To be included in the present study, patients have to be adults (≥18 years of age) newly-initiated on warfarin or rivaroxaban 15 mg (index event, index drug), have at least 365 days of continuous medical and prescription benefits prior to the index event (baseline period), at least two diagnosis codes for NVAF (on outpatient or inpatient claims, at two different days) and at least one diagnosis code (inpatient or outpatient) indicating renal dysfunction in the baseline period.

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

Renal impaired

Estimated number of subjects

11000

Study design details

Outcomes

Ischemic stroke,Intracranial hemorrhage,Bleeding-related hospitalization, Composite endpoint, which is defined as the occurrence of ischemic stroke or intracranial hemorrhage, Progression to stage 5 chronic kidney disease, kidney failure or need for dialysis

Data analysis plan

Stabilized inverse probability of treatment weighting (IPTW) methodology based on the propensity score will be utilized to adjust for potential confounding. Additionally, a propensity score matching analysis and a conventional multiple logistic regression analysis will be conducted. The incidence rates of the study outcome measures will be reported as the number of events per 100 person-years. Cox proportional hazards regression model will be applied to estimate adjusted hazard ratios.

Documents

Study results

19721_CALLIPER_EU PAS Abstract_2019-07-31_Redacted.pdf (221.14 KB)

Study report

19721_CALLIPER_Clinical Study Report_2019-07-31_Redacted.pdf (9.89 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

No