Comparative effectiveness of rivaroxaban and warfarin for stroke prevention in multi-morbid patients with nonvalvular atrial fibrillation

First published: 04/12/2017

Last updated: 01/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS21800

Study ID

36744

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 Contact Bayer AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/11/2017

Actual: 02/11/2017

Study start date
Planned: 01/12/2017

Actual: 01/12/2017

Date of final study report
Planned: 30/10/2020

Actual: 07/07/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

19859_CSP_V2.0_2019-01-31_redacted.pdf (3.27 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:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objective in this study is to evaluate the combined end point of stroke or systemic embolism (SSE), and major bleeding in NVAF patients treated with rivaroxaban vs. VKA.

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

The source population of this study will be all the insured individuals included in the Truven Health MarketScan Commercial Claims and Medicare Supplemental Databases (Truven MarketScan).

To be included in this study patients would have to:

• be oral anticoagulant naive during the 365 days before the day of the first qualifying oral anticoagulant (rivaroxaban or VKA) dispensing, and

• have ≥365 days of continuous medical and prescription coverage before initiation of oral anticoagulation (which serves as the study's baseline period)

Exclusion criteria:

• <18 years of age

• <2 International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification diagnosis codes for atrial fibrillation

• valvular heart disease

• transient cause of NVAF

• venous thromboembolism

• hip or knee arthroplasty

• malignant cancer

• pregnancy

• >1 oral anticoagulant prescribed (on index date)

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

Non-valvular atrial fibrillation (NVAF) patients

Estimated number of subjects

99999

Study design details

Outcomes

1.Stroke2.Systemic embolism3.Major bleeding, 1.Hemorrhagic stroke2.Ischemic stroke3.Subtypes of major bleeding

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Data analysis plan

Baseline patient characteristics will be analyzed using descriptive statistics. Categorical data will be reported as proportions, while continuous data will be reported as means±standard deviations or medians with interquartile ranges.The incidence of primary and secondary study end points will be reported as the number of events per 100 person-years anticoagulant exposure and calculated as the number of patients with ≥1 documented event divided by each respective cohorts’ time at risk. Cox proportional hazards regression will

be performed on the matched cohorts and results reported as hazard ratios and 95% confidence intervals.Individuals enrolled in the MarketScan databases are largely representative of the United States population in terms of age, sex, and type of health insurance coverage.While the MarketScan claims databases are based on a large sample it may contain biases or fail to generalize well to other populations.

Documents

Study results

19859_EU PAS Abstract_Redacted_V1.0_2020-07-07.pdf (426.5 KB)

Study report

19859_Clinical Study Report_Redacted_V 1.0_2020-07-07.pdf (2.08 MB)

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 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