Real-world evidence for non-valvular atrial fibrillation patients treated with oral anticoagulation in the Nordics (REATTAIN)

First published: 30/01/2020

Last updated: 31/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS33167

Study ID

45933

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Finland
- [ ] Norway
- [ ] Sweden

Study description

Oral anticoagulant (OAC) treatment with either vitamin K antagonists (VKAs) or non-vitamin K antagonist oral anticoagulants (NOACs) is essential for the prevention of stroke or systemic embolism (SE) in patients with atrial fibrillation. While there are significant number of real-world evidence (RWE) publications on the use of NOACs for stroke prevention, evidence from routine clinical practice on the use and outcomes of reduced doses of NOACs is scarce. This study aims to assess the effectiveness and safety of these regimens compared to VKA for stroke prevention in patients with non-valvular atrial fibrillation (NVAF). The study will evaluate patients treated in routine clinical practice across the Nordic countries.

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

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Institution

Contact details

Study institution contact

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

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/07/2019

Study start date

Planned: 01/03/2020

Actual: 01/03/2020

Date of final study report

Planned: 31/08/2022

Actual: 26/04/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

20030_Study Protocol_V1.0_2019-08-19_redacted.pdf (5 MB)

20030_Study Protocol_Redacted_V2.2_2020-11-26.pdf (961.65 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 type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To describe the risk of ischemic stroke (IS)/systemic embolism (SE), and intracranial hemorrhage (ICH) in patients with NVAF initiating treatment with reduced doses of individual NOACs (rivaroxaban, apixaban, dabigatran) compared to VKA (warfarin)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

APIXABAN

DABIGATRAN ETEXILATE

RIVAROXABAN

WARFARIN

Medical condition to be studied

Atrial fibrillation

Population studied

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)

Estimated number of subjects

70000

Study design details

Outcomes

1. Number of participants with ischemic stroke (IS) or systemic embolism (SE),
2. Number of participants with intracranial haemorrhage (ICH)

Data analysis plan

Risk of outcomes will be estimated by calculating cause-specific hazard ratios using Cox regression models

Documents

Study results

20030_EU PAS Abstract_Redacted_V1.0_2024-04-26.pdf (232.66 KB)

Study report

20030_Study Report_Redacted_V1.0_2024-04-26.pdf (3.2 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 source(s)

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

NorPD

Data sources (types)

Administrative healthcare records (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