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

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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/45933

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
Ongoing

Research institution and networks

Institutions

Bayer AG
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Institution

Contact details

Study institution contact
Bayer Clinical Trials BAYER AG
Study contact

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Primary lead investigator
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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

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
WARFARIN
DABIGATRAN ETEXILATE
RIVAROXABAN
APIXABAN

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

Data management

Data sources

Data source(s)
Danish registries (access/analysis)
National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other
Danish Registries (access/analysis), The Swedish prescribed drug register, NorPD

Data sources (types)
Administrative data (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