A Post-marketing Retrospective nOn-interventional study using naTionwide registries and electronic medical records to investigate the real-life Effectiveness and major bleeding Complications of oral anTicoagulants in Norwegian non-valvular Atrial Fibrillation patients (PROTECT-AF)

First published: 24/10/2018

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS26001

Study ID

45790

DARWIN EU® study

No

Study countries

Norway

Study description

A nationwide observational study investigating the effectiveness and bleeding complications of NOACs vs. VKA in non-valvular atrial fibrillation patients.

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

First published: 01/02/2024

Last updated: 01/02/2024

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: 10/09/2018

Actual: 10/09/2018

Study start date
Planned: 31/10/2018

Actual: 31/10/2018

Date of final study report
Planned: 29/02/2020

Actual: 29/02/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

19468_CSP_V1.0_2018-09-06_Redacted.docx.pdf (968.83 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 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:

To assess the effectiveness and safety of NOACs vs. VKA in patients with non-valvular atrial fibrillation.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

RIVAROXABAN

APIXABAN

DABIGATRAN

WARFARIN

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

The study population will comprise all adult OAC naïve NVAF patients in Norway who filled a prescription for an OAC (rivaroxaban, apixaban, dabigatran, warfarin) in the study period, defined as from 1 January 2014 to 30 June 2018 (or later depending on availability of data).

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

70000

Study design details

Outcomes

- Ischemic stroke- Intracranial hemorrhage, - Overall stroke- Systemic embolism- Myocardial infarction- All-cause mortality- Major bleeding- Demographic characteristics- Clinical characteristics- Drug utilization patterns

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Data analysis plan

Descriptive statistics will be used to present the data where continuous variables will be summarized as mean, standard deviation, median, minimum and maximum. Categorical variables will be described by frequencies and related percentages. Summaries will be reported separately for the elderly +75 years (cohort 1 and 2) and patients with renal impairment (cohort 2). Annual frequency of different OAC treatment during the study period in addition to

adherence to each NOACs (high, moderate, low, and poor) will be presented. Also a separate analysis will be done to characterize patients with NVAF who have not been treated with OAC.

Documents

Study results

EU-PAS_Abstract_2020-11-26.pdf (397.88 KB)

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)

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