Major bleeding in patients with atrial fibrillation treated with apixaban versus warfarin in combination with amiodarone: the APIXAMIO study

First published: 21/10/2021

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS43681

Study ID

49753

DARWIN EU® study

No

Study countries

☐ Sweden

Study description

By merging and analyzing various Swedish national registry data the present real-world study will describe the patient characteristics in patients treated with amiodarone in combination with either apixaban or warfarin, and if deemed possible after feasibility assessment, compare safety outcomes, in terms of bleeding, in these two patient cohorts.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Study timelines

Date when funding contract was signed

Planned: 01/06/2021

Actual: 01/06/2021

Study start date

Planned: 26/11/2021

Actual: 26/11/2021

Data analysis start date
Planned: 25/11/2021

Actual: 15/11/2022

Date of final study report
Planned: 15/10/2023

Actual: 19/09/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

Protokoll (2021-10-05).pdf (294.55 KB)

Protocol B0661167 APIXAMIO Amendment 2_29Sept2022_Final.pdf (377.32 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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To describe the clinical characteristics in patients with AF treated with amiodarone in combination with apixaban or warfarin. To compare the occurrence of major bleedings in patients with atrial fibrillation treated with the combination of apixaban + amiodarone versus the combination of warfarin + amiodarone.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective registry-based observational study

Study drug and medical condition

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

APIXABAN

WARFARIN

AMIODARONE

Medical condition to be studied

Atrial fibrillation

Additional medical condition(s)

Oral anticoagulation-associated bleedings

Population studied

Short description of the study population

The study population included patients aged 18 years or older diagnosed with atrial fibrillation (AF) treated with amiodarone in combination with apixaban or warfarin between 1 June 2013 and 31 December 2018, identified from Swedish national registries.

Inclusion criteria:

1. Patients that have one or more AF (ICD-10 I48) diagnosis registered in the National Patient Register
2. Patients ≥ 18 years
3. Patients who had a filled prescription for amiodarone and apixaban or warfarin during the identification period

Exclusion criteria:

1. Patients with valvular AF (defined as patients with mechanical heart valves (Z952) implanted before index, or with a diagnosis of mitral stenosis before and including index date (I342, I050, I052, Q232).

2. Patients with an acute venous thromboembolism 6 months period before and including the index date (I26, I801, I802, I803, I808, I809, I822, I823, I828, I829, O223, O871, O882).
3. Patients with diagnosis or procedure-code for hip/knee replacement surgery within 6 weeks before and including index date (NFB, NFC, NGB, NGC, NFG, NGG).
4. Diagnosis codes indicating pregnancy 9 months before and including index date (A34, O00-O99, Z33, Z34, Z35, Z36, Z37, Z39, Z640, Z641).
5. Patients dispensing simultaneously more than one OAC (ATC code B01AA03, B01AE07, B01AF01, B01AF02, B01AF03) during the identification 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

Other

Special population of interest, other

Patients with atrial fibrillation

Estimated number of subjects

10000

Study design details

Outcomes

If the feasibility analysis after assessing the descriptive data are robust and valid enough to conduct a comparative safety analysis between apixaban and warfarin in combination with amiodarone in terms of bleeding the primary outcome will be: • To compare the occurrence of major bleeding in patients treated with amiodarone in combination with apixaban versus warfarin., Intracranial bleeding Gastro-intestinal bleeding Other bleedings leading to hospitalization

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Data analysis plan

Kaplan-Meier estimates with accompanying at risk tables for the treatment analysis will be plotted to illustrate all outcomes with regard to apixaban+amiodarone versus warfarin+amiodarone, before and after the propensity score matching. Matched cohorts will be compared with regard to outcome events using Cox regression analysis and with adjustments for relevant covariates.

Documents

Study report

B0661167 Non Interventional Study Report 19 September 2023.pdf (703.89 KB)

Study, other information

B0661167 Non Interventional Study Report Abstract 19 September 2023.pdf (144.5 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 source(s), other

Swedish Prescribed Drug Register

Data sources (types)

Disease registry

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