The use of NOAC for atrial fibrillation in patients after biologic valvular replacement or valvuloplasty

First published: 10/12/2019

Last updated: 26/11/2020

Study | Finalised

Administrative details

EU PAS number

EUPAS31606

Study ID

38312

DARWIN EU® study

No

Study countries

☐ Sweden

Study description

A retrospective registry-based observational study using data between 2010-2017 from the SWEDEHEART, and Swedish administrative health databases. The objective was to compare outcomes in patients with atrial fibrillation undergoing biological valve surgery, TAVI or valvuloplasty between patients treated with either apixaban or warfarin. According to protocol, after primary data analysis, a pre-planned feasibility assessment was conducted, which did not support moving forward with a comparative effectiveness study mainly due to low statistical power. A decision to not conduct any outcome analysis was taken 7th of April 2020.

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Angelo Modica

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 21/11/2019

Study start date
Planned: 26/08/2019

Actual: 26/08/2019

Data analysis start date
Planned: 11/12/2019

Date of interim report, if expected
Actual: 10/02/2020

Date of final study report
Planned: 17/12/2019

Actual: 05/11/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

B0661136_STUDY PROTOCOL_Final_191206.pdf (1.45 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:

Human medicinal product

Disease /health condition

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:

Describe the patterns of OACs and outcomes for patients with AF after biological valve surgery, transcatheter valve intervention or after valvuloplasty.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Register-based observational study, Non-randomized registry study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AF02) apixaban

apixaban

(B01AA03) warfarin

warfarin

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

The patient cohort will be identified using the SWEDEHEART national quality register and will include all patients treated with either biological valve surgery, transcatheter valve intervention, or valvuloplasty performed during 2010-2017.

Inclusion criteria

Patients must meet all of the following inclusion criteria to be eligible for inclusion in the study:

1. > 18 years at discharge.
2. Valvular disease requiring valve surgery, transcatheter valve intervention, or valvuloplasty
3. Registred in SWEDEHEART for the index valve intervention
4. Atrial fibrillation/flutter registred in SWEDEHEART or in the National Patient Register (NPR) before index intervention or during follow-up.

Exclusion criteria
Patients meeting any of the following criteria will not be included in the study:
1. Treatment with a mechanical valve prosthesis
2. Prescription of more than one type of OAC at discharge
3. Death before discharge from the index valve intervention

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

5000

Study design details

Outcomes

To evaluate the association between apixaban versus warfarin treatment and the combination of all-cause death, stroke (ischemic and hemorrhagic), systemic embolization and major bleeding from 3 months post intervention to the end of follow up. To evaluate the association between apixaban versus warfarin treatment and the combination of all cause-death, stroke (ischemic and hemorrhagic), systemic embolization and major bleeding from hospital discharge post intervention to the end of follow up.To evaluate the separated endpoints, from hospital discharge post intervention and from 3 months post intervention.

Data analysis plan

Step 1. To assess the feasibility, with respect to data quality, crude event counts by type of OAC and power estimation, to conduct a comparative analysis between apixaban and warfarin using the specified data. Step 2.(If the result of feasability assessment is positive, step 1)To evaluate the association between apixaban versus warfarin treatment on the composite endpoint of all-cause death, stroke (ischemic and hemorrhagic), systemic embolization and major bleeding from 3 months post intervention to the end of follow up.Methodology: To compare the risk of outcome events across the study cohorts, time to event analysis will be undertaken, using adjusted Cox regression models for intention to treat and time-varying Cox regression models for intention to treat and time-varying Cox regression models for on treatment analyses

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)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

The Swedish prescribed drug register

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Other

Data sources (types), other

Prospective patient-based data collection

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