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

PURI
https://redirect.ema.europa.eu/resource/38312

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 data collection

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
100000144761
apixaban
100000094255
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

Data sources

Data source(s)
National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other
The Swedish prescribed drug register

Data sources (types)
Administrative data (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