Beyond Pooled – Part of the BEYOND study program (Benefit of NOACs study of non-valvular AF patients in nordic countries) (BEYOND Pooled (Denmark, Norway, Sweden))

First published: 23/05/2016
Last updated: 23/04/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/33157

EU PAS number
EUPAS13470

Study ID
33157

DARWIN EU® study
No

Study countries
Denmark
Norway
Sweden

Study description
The overall aim of this study is to evaluate effectiveness and safety of each NOAC compared with warfarin in treatment-naïve initiators of anticoagulants with NVAF in routine clinical practice in Denmark, Norway and Sweden. The study will use pooled data from nationwide registries in Denmark, Norway and Sweden.

Study status
Finalised

Research institution and networks

Institutions

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark
First published: 20/07/2021
Last updated
02/04/2024

Institution
Educational Institution
ENCePP partner

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden
First published: 24/03/2010
Last updated
23/04/2024

Institution
Educational Institution
Laboratory/Research/Testing facility
Not-for-profit
ENCePP partner

Department of Clinical Epidemiology Olof Palmes Allé 43-45, Department of Global Public Health and Primary Care Kalfarveien 31, NO-5018 Bergen, Norway

Contact details

Study institution contact
Aaron Jenkins

Study contact

Aaron.Jenkins@pfizer.com
Primary lead investigator
Vera Ehrenstein
Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
15/12/2015

Study start date
Planned:
01/10/2017
Actual:
17/08/2018

Data analysis start date
Planned:
22/11/2018
Actual:
30/11/2018

Date of final study report
Planned:
31/08/2019
Actual:
29/07/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer, Inc.

Study protocol

BEYOND Pooled Protocol FINAL approved 28 Sep 2017.pdf(1.24 MB)

B0661103 BEYOND Pooled Protocol 2018-07-05 amendment 1_1 signed off.pdf(1.05 MB)

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Other study registration identification numbers and links

CCTR protocol number: B0661103

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 data collection

Main study objective:
To evaluate effectiveness and safety of each NOAC compared with warfarin in treatment-naïve initiators of anticoagulants with NVAF in routine clinical practice in Denmark, Norway

and Sweden.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine
Eliquis
Pradaxa
Xarelto

Medical condition to be studied
Atrial fibrillation

Population studied

Short description of the study population
Treatment-naïve adults in the source population diagnosed with Atrial fibrillation (AF), with a dispensing of apixaban, rivaroxaban or dabigatran (‘the NOACs’) or warfarin during the study population identification period.

Patients had to meet all of the following inclusion criteria on the index date:
• Be alive and of age 18 years or older;
• A dispensing of apixaban, dabigatran, rivaroxaban, or warfarin between 01 January 2013 and 31 December 2016;
• Diagnosis of AF recorded up to 5 years before or up to 60 days after the index date.

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
20000

Study design details

Outcomes
Stroke/systemic embolism and major bleeding. Ischaemic stroke, haemorrhagic stroke, major intracranial bleeding, major gastrointestinal bleeding, acute myocardial infarction, or death of any cause, any hospitalized bleeding, and composite outcome of ischemic stroke, systemic embolism, myocardial infarction, or all-cause mortality.

Data analysis plan
To compare risks of the endpoints across the study cohorts, time to event analysis will be undertaken, using Cox proportional-hazards regression, with death as competing risk for endpoints not including death. Crude and adjusted hazard ratios (HRs) and 95% confidence intervals (CI) will be estimated for initiators of each NOAC. Follow-up will end on the date of a given endpoint, date of death (for non-death endpoints), date of discontinuation of or switch from the index OAC, date of emigration, or 31 December 2016, whichever comes first. A patient will be considered on-treatment from the date of initiation of the on-study OAC and for the subsequent number of days corresponding to the number of tablets in a package for rivaroxaban (used once daily) or half the number of tablets in a package for dabigatran and apixaban (used twice daily).

Documents

Study results
BEYOND POOLED Abstract 25JUL2019.pdf(147.14 KB)
Beyond POOLED Final Report 25JUL2019.pdf(4 MB)

Data management

Data sources

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

Data source(s), other
NorPD

Data sources (types)
Administrative data (e.g. claims)

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