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

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 institutions and networks

Institutions

Aarhus University & Aarhus University Hospital CLINICAL EPIDEMIOLOGY AND DATA SCIENCE, DEPARTMENT OF CLINICAL MEDICINE

Denmark

First published: 20/07/2021

Last updated: 20/10/2026

Institution | Educational Institution

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 02/06/2026

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

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Contact details

Study institution contact

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Study contact

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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 use of data

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

Medicinal product name

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

20.000

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

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)

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

NorPD

Data sources (types)

Administrative healthcare records (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