A retrospective nationwide register study to characterize and compare non-valvular atrial fibrillation (NVAF) patients in Norway treated with novel oral anticoagulants (NOACs) and warfarin on drug utilization patterns, discontinuation and bleeding complication rates (Beyond Study Norway)

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Study Planned

Administrative details

EU PAS number

EUPAS8611

Study ID

8612

DARWIN EU® study

No

Study countries

Norway

Study description

The study aims to describe the drug utilization patterns and characteristics of patients on oral anticoagulant therapy (OAC) and to describe and compare the discontinuation rates and the risk of bleeding complications between different OAC therapies. The study will be undertaken on nation-wide registries in Norway during the early post-marketing period of the novel oral anticoagulants. The study will be undertaken in Norway and will include all adult patients with NVAF and a prescription dispensed on either a NOAC or warfarin in the study period (01 January 2013 to end of September 2014 depending on data availability).

Study status

Planned

Research institutions and networks

Institutions

Lifandis

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Christian Jonasson

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/11/2014

Study start date

Planned: 01/05/2015

Data analysis start date

Planned: 01/09/2015

Date of interim report, if expected

Planned: 15/10/2015

Date of final study report

Planned: 30/11/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc.

Study protocol

Protocol Beyond-Norway final version 12Dec2014.pdf (898.82 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

Primary objective is to describe and compare the clinical and patient characteristics such as CHADS2, CHA2DS2-VASc and HAS-BLED score, previous OAC use, bleeding history, concomitant medications and co-morbidities of all NVAF patients who initiated an OAC in the study period, overall and separately by each OAC (apixaban, dabigatran, rivaroxaban, warfarin), by OAC-switch status and previous OAC use

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

APIXABAN

RIVAROXABAN

DABIGATRAN

WARFARIN

PHENPROCOUMON

Medical condition to be studied

Atrial fibrillation

Population studied

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

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

72.000

Study design details

Outcomes

Primary objective is to describe and compare the clinical and patient characteristics such as CHADS2, CHA2DS2-VASc and HAS-BLED score, previous OAC use, bleeding history, concomitant medications and co-morbidities of all NVAF patients who initiated an OAC in the study period, overall and separately by each OAC (apixaban, dabigatran, rivaroxaban, warfarin), by OAC-switch status and previous OAC use, To determine predictive factors of patients initiating each OAC as monotherapy (without a switch from a different OAC).To identify predictive factors of switching.To identify predictive factors of discontinuation.To compare clinically relevant bleedings and major bleeding rates for NVAF patients treated with OAC therapy.

Data analysis plan

Patient characteristics for each OAC group will be described by the mean, standard deviation, median, first and third quartiles, and minimum and maximum for continuous variables, and by the number and percentage of patients in each category for categorical variables. Regression analysis will be the primary analytical approach with both unadjusted and adjusted models to be estimated and patient characteristics, OAC group, previous OAC use, co-morbidities, concomitant medications measured at baseline as candidate independent variables. Predictive performance of the final models will be assessed by the c-statistic. For time to event analyses our primary approach will be Cox proportional hazard regression analysis with the same candidate independent variables as above. A propensity score matching approach will also be considered as an analysis option.

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

NPR (Norwegian Patient Register) Norway, 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