Oral Anticoagulant Use in Patients with Non Valvular Atrial Fibrillation: Analysis of Electronic Medical Record Data

First published: 03/02/2017

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Study Planned

Administrative details

EU PAS number

EUPAS17684

Study ID

17685

DARWIN EU® study

No

Study countries

United States

Study description

This retrospective cohort study will involve adult NVAF patients treated with an oral anti-coagulant (OAC). Key study outcomes include safety and effectiveness endpoints.

Study status

Planned

Research institutions and networks

Institutions

Boston Health Economics

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Institution

Contact details

Study institution contact

Masseria Cristina cristina.masseria@pfizer.com

Study contact

cristina.masseria@pfizer.com

Primary lead investigator

Masseria Cristina

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/10/2017

Study start date
Planned: 20/01/2017

Data analysis start date
Planned: 17/02/2017

Date of interim report, if expected
Planned: 28/02/2017

Date of final study report
Planned: 24/03/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer, Inc.

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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

Investigation of safety and effectiveness outcomes for NVAF patients taking OACs.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ELIQUIS

XARELTO

PRADAXA

Medicinal product name, other

Coumadin

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)

Estimated number of subjects

20.000

Study design details

Outcomes

Bleeding, stroke, embolism

Data analysis plan

Propensity score matching will be conducted. Standard statistical measures will be calculated (e.g. mean, median, mode) along with hazard ratios.

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 sources (types)

Other

Data sources (types), other

Humedica EMR

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