Real-world Comparisons of Stroke, Major Bleeding, Myocardial Infarction, Acute Limb Ischemia and Death among Non-Valvular Atrial Fibrillation Patients Diagnosed With Coronary Artery Disease/Peripheral Arterial Disease who Initiated Oral Anticoagulation Therapies (CAD PAD)

First published: 05/05/2017

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS18970

Study ID

23575

DARWIN EU® study

No

Study countries

United States

Study description

The study will be a longitudinal retrospective cohort analysis using the CMS fee-for-service (FFS) Medicare database. The study period will be from January 1, 2012 through December 31, 2014 or until the last date of the data cut available at the time of execution of the study.This study will evaluate the patient profiles, current antithrombotic patterns and real-world clinical outcomes among NVAF patients with CAD and/or PAD.Aim 1: To compare the risk of myocardial infarction (MI), stroke, acute limb ischemia, all-cause death and a composite of these endpoints among patients initiating OACs (warfarin, apixaban, rivaroxaban and dabigatran). Aim 2: To compare the risk of major bleeding among patients initiating OACs.Aim 3: To compare the risk of stroke and stroke/SE among patients initiating OACs.Aim 4: To compare healthcare resource use and costs among patients initiating different OACs.Aim 5: To describe the baseline demographic and clinical characteristics among patients initiating OACs (warfarin, apixaban, rivaroxaban and dabigatran)

Study status

Finalised

Research institutions and networks

Institutions

SIMr STATinMED

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Di Fusco Manuela

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 02/01/2017

Study start date

Planned: 09/05/2017

Actual: 09/05/2017

Date of final study report

Planned: 11/04/2018

Actual: 11/04/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

Pfizer_CAD_PAD_NOAC NI Study Protocol_04MAY2017.pdf (795.05 KB)

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The main objective of this study is to collect and analyze clinical and cost-related outcome measures for treatment naïve NVAF patients on either apixaban or warfarin using a US claims database.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective cohort analysis

Study drug and medical condition

Medicinal product name

ELIQUIS

PRADAXA

XARELTO

Medicinal product name, other

Coumadin

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Adult patients who were prescribed oral anticoagulants were selected from the Medicare database between January 1, 2013 and December 31, 2014 or until the last date of the data cut available at the time of execution of the study.

Age groups

- 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

Patients with atrial fibrillation

Estimated number of subjects

10.000

Study design details

Outcomes

Bleeding-related outcomes, Health resource utilization/cost outcomes

Data analysis plan

Descriptive analyses, including means, medians, and standard deviations will be conducted for continuous variables. Numbers and percentages will be provided for dichotomous and polychotomous variables. Bivariate comparisons of baseline characteristics and outcomes measures will be provided. Appropriate tests will be used based on the distribution of the measure. The cumulative incidence rate for clinical outcomes will be calculated. Multivariate analysis or propensity score matching will be conducted.

Documents

Study results

Pfizer_Medicare_NVAF_CAD-PAD_Study Report_11APR2018.pdf (3.08 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 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

Unknown