Hospital Readmissions Among Nonvalvular Atrial Fibrillation Patients Treated with Oral Anticoagulants in the U.S.

First published: 13/08/2018

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Study Finalised

Administrative details

EU PAS number

EUPAS25238

Study ID

37527

DARWIN EU® study

No

Study countries

United States

Study description

The study will address the following primary research question: What is the frequency of readmission for major bleeding (MB) within 1 month after an index hospitalization for NVAF patients treated with apixaban, dabigatran, rivaroxaban, or warfarin?

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

Christine L. Baker Christine.L.Baker@pfizer.com

Study contact

Christine.L.Baker@pfizer.com

Primary lead investigator

Christine L. Baker

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 09/03/2018

Study start date
Actual: 01/08/2018

Date of final study report
Actual: 27/07/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

PremierDB_Hospital_OAC_AF_Readmission_Protocol_v9.pdf (635.99 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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Major Bleeding

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of the study is to evaluate and compare 1-month MB-related readmission rates of hospitalized NVAF patients treated with dabigatran, rivaroxaban, or warfarin vs. apixaban.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ELIQUIS

Population studied

Short description of the study population

Adult patients (age ≥18 years) hospitalized for NVAF, based on a primary or secondary discharge diagnosis code indicating NVAF, were identified from the Premier
Hospital database between January 1, 2013 and June 30, 2017. Patients who received apixaban, dabigatran, rivaroxaban, or warfarin during any time of the hospitalization (from admission to discharge) were identified and grouped into study cohorts based on the oral anticoagulant (OAC) initiated. The first of such NVAF hospitalizations were defined as the index hospitalization. Patients with more than one type of OAC drug usage during the index hospitalizations were excluded so that patients can be exclusively assigned into each of the OAC patient cohorts.

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

Non valvular atrial fibrillation patients

Estimated number of subjects

1

Study design details

Outcomes

MB-related Readmission, All-cause Readmission, Stroke-related Readmission

Data analysis plan

Means ± standard deviations, and medians will be provided for continuous variables. Numbers and percentages will be provided for dichotomous and polychotomous variables. Bivariate comparisons of baseline patient and hospital characteristics and readmission measurements will be provided, with appropriate tests (e.g. ANOVA test, chi-square test) used based on the distribution of the measure. A propensity score matching (PSM) 1:1 technique will be used to control for confounders when comparing each of the OAC cohorts vs. the apixaban cohort. A logistic regression analysis will be carried out on the matched patient cohorts to further evaluate the potential impact of treatment with the different OACs vs. treatment with apixaban on 1-month MB-related and all-cause readmissions.

Documents

Study results

Approved NVAF Premier NI Final Study Report.docx.pdf (2.73 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

No