Clinical and Economic Outcomes and Treatment Patterns for Non-Valvular Atrial Fibrillation Patients Who Newly Initiated Oral Anticoagulants in the US Medicare Population

First published: 10/08/2018

Last updated: 06/10/2020

Study Finalised

Administrative details

EU PAS number

EUPAS25230

Study ID

37513

DARWIN EU® study

No

Study countries

United States

Study description

This study will add “real-world” evidence for the comparative risks of stroke/SE, major bleeding, related health care costs, and treatment patterns among elderly NVAF patients who initiated OACs.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

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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: 29/07/2017

Study start date
Actual: 08/08/2017

Date of final study report
Actual: 31/08/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

SIMR_Pfizer_Apixaban_Medicare_Protocol_03NOV2017.pdf (583.45 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

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

1. Compare the risk of stroke/SE and major bleeding between NVAF patients who initiated OACs (warfarin, apixaban, rivaroxaban, dabigatran, or edoxaban).2. Compare all-cause and stroke/SE- and major-bleeding-related health care costs among NVAF patients who initiated OACs.3. Compare treatment patterns (discontinuation, switch, and dose) among the cohorts.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Longitudinal retrospective cohort analysis using the US FFS Medicare database

Study drug and medical condition

Medicinal product name

ELIQUIS

Medical condition to be studied

Atrial fibrillation

Venous thrombosis

Population studied

Short description of the study population

Non-valvular atrial fibrillation (NVAF) patients prescribed an oral anticoagulants (OAC) between 01-Jan-2013 to 31-Dec-2015 (or most recent data available) with continuous health plan enrollment during their baseline period were included in the study. The first Several direct oral anticoagulants (DOAC) pharmacy claim date during the identification period was designated as the index date. The first warfarin prescription date was designated as the index date for patients without any DOAC claim. For the annual prevalence calculation, NVAF patients aged ≥65 years with continuous enrollment during each year from 2012 to 2015 were included as the numerator. The Medicare population aged ≥65 years with

continuous enrollment during each year from 2012 to 2015 was included as the denominator.

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

Non-valvular atrial fibrillation (NVAF) patients

Estimated number of subjects

1

Study design details

Outcomes

Stroke/SE, Composite clinical outcomes, MB and related cost outcomes

Data analysis plan

Descriptives, PSM, Cox Proportional

Documents

Study results

NVAF Medicare 2015 NI Final study report.pdf (1.01 MB)

Study publications

Amin A, Keshishian A, Dina O, et al. Comparative clinical outcomes between dire…

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