Predictors of Treatment and the Comparative Clinical and Economic Outcomes among Non-Valvular Atrial Fibrillation Patients Treated versus Untreated with Oral Anticoagulant Therapy (NVAF Diagnosed Untreated)

First published: 08/07/2019

Last updated: 16/09/2021

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/43073

EU PAS number

EUPAS30448

Study ID

43073

DARWIN EU® study

No

Study countries

☐ United States

Study description

This study will estimate prevalence of newly diagnosed but untreated NVAF patients, add real-world evidence for the predictors of treatment among newly diagnosed NVAF patients. In addition, it will evaluate the risks of major bleeding, stroke/SE, and death by comparing OAC treatment versus no OAC treatment. The comparative health care costs and utilization will also be evaluated.

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Patrick Hlavacek

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 14/08/2018

Study start date
Planned: 26/06/2019

Actual: 26/06/2019

Date of final study report
Planned: 30/09/2021

Actual: 11/07/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

SIMR_Pfizer_Untreated_Medicare_Protocol_13JUN2019_clean (004).pdf(751.72 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:

Disease epidemiology

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

1.Estimate patients ever-treated and never-treated with OACs and the predictors of OAC treatment among elderly Medicare NVAF patients. 2.Compare the risk of stroke/SE & major bleeding and related costs among elderly patients treated versus untreated with OACs in the Medicare NVAF population.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

ELIQUIS

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Elderly patients (aged ≥65 years) will be required to have ≥1 inpatient or ≥ 2 outpatient medical claims (the 2 outpatient claims are ≥7 days apart) for AF during the identification period for the primary and secondary objectives. For the primary objective, two mutually-exclusive NVAF patient cohorts will be created: ever treated with OAC and nevertreated with OAC. For the secondary objective assessing clinical and healthcare utilization and costs, treatment status will be a time-varying covariate and ever-treated patients will contribute time-not-on-treatment to untreated effect.

Inclusion Criteria

1) Patients had ≥1 inpatient claim or ≥2 outpatient claims (at least 7 days gap between the two outpatient claims) for AF (international classification of diseases, ninth revision, clinical modification [ICD-9-CM] code 427.31; ICD-10-CM: I480-I482, I4891) during 01JAN2013-31DEC2017. The first AF diagnosis

claim dates during the identification period were designated as the index date24;
2) Patients had 12-months of continuous health plan enrollment with medical and pharmacy benefits (Medicare Part A, B, and D) before the index date and 6-month continuous health plan enrollment with medical and pharmacy benefits (Medicare parts A, B, and D) after the index date;
3) Patients had CHA2DS2-VASc score ≥2 during 12 months on or before the index date;
4) Aged ≥65 years on the index date.

Exclusion Criteria
1) Excluded patients with AF diagnosis prior to the index date;
2) Excluded patients with medical claims indicating diagnosis of mitral valvular heart disease or valve replacement procedure (see Appendix) during the 12 months prior to or on the index date;
3) Excluded patients who had a pharmacy claim for apixaban, dabigatran, edoxaban, rivaroxaban, or warfarin during the 12 months pre-index period.

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

Atrial fibrillation patients

Estimated number of subjects

1204507

Study design details

Outcomes

Predictors of treatment, Major bleeding, Stroke/SE, Major bleeding related costs, Stroke/SE related costs/ All cause health care utilization, All cause costs

Data analysis plan

means, medians, and standard deviations will be provided for continuous variables. When performing descriptive analysis of categorical data, numbers and percentages will be provided for dichotomous and polychotomous variables. Bivariate comparisons of baseline characteristics and outcomes measures will be provided. Appropriate tests (eg, t-test, chi-square test) will be used based on the distributions of the measures. The cumulative incidence rate for clinical outcomes (major bleeding, stroke/SE, and death) will be calculated. A logistic regression will be used to examine risk factors associated with OAC treatment (OAC, DOAC, or warfarin)/non-treatment with OACs and DOAC treatment/warfarin treatment.

Documents

Study results

SIMR_Pfizer_Untreated_FinalReport.pdf(3.07 MB)

Data management

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