AF In Real practice on Management of oral Anticoagulation (AFIRMA 4.0)

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Study Finalised

Administrative details

EU PAS number

EUPAS36330

Study ID

50344

DARWIN EU® study

No

Study countries

Spain

Study description

Options for anticoagulation have been expanding steadily over the past few decades, providing a greater number of oral anticoagulant (OAC) agents for prevention and management of thromboembolic disease. In addition to the

standard treatment with vitamin K antagonists (VKA) (i.e. warfarin and acenocumarol), new oral anticoagulants (non-vitamin K antagonist oral anticoagulants, NOACs) that directly target the activity of thrombin inhibitor (dabigatran) and the factor Xa inhibitors (rivaroxaban, apixaban, and edoxaban) have recently revolutionized thromboprophylaxis for stroke and systemic embolism (SE) in patients with non-valvular atrial fibrillation (NVAF). Appropriate use of these agents requires knowledge of their individual characteristics, risks, and benefits. Thus, advantages and disadvantages of each agent must be individualized to the patient and clinical setting. NOACs are the preferred choice in those NVAF populations with increased risks of both thromboembolic and bleeding events. However, the proper use of NOACs requires a careful approach to many practical aspects. In this context, we propose to use SAVANA, an innovating data-driven system based on Natural Language Processing (NLP) and big data techniques, designed to analyse unstructured data contained in electronic medical files from NVAF patients who were prescribed OACs (apixaban, dabigatran, rivaroxaban, edoxaban, acenocumarol and warfarin). The study period will be from January 2014 through December 2018 (or most recent data available). The study will occur over three phases: an initial one describing patient characteristics and treatment pathways, the second one with a description of the minor bleeding events and comparative analysis between treatments, and a third one describing stroke/SE and major bleedings and a comparative analysis between treatments.

Study status

Finalised

Research institutions and networks

Institutions

Hospital Arnau de Vilanova de Valencia (HAV)

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Institution

Contact details

Study institution contact

Susana Fernandez de Cabo

Susana.FernandezdeCabo@pfizer.com

Study contact

Susana.FernandezdeCabo@pfizer.com

Primary lead investigator

Susana Fernandez de Cabo

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/07/2020

Actual: 23/07/2020

Study start date

Planned: 15/09/2020

Actual: 17/09/2020

Date of final study report
Planned: 30/11/2023

Actual: 30/11/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

PFIZER

Study protocol

Versión redactada Protocolo AFIRMA 4.0.pdf (25.43 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

B0661131/PFI-API-2019-01

Methodological aspects

Study type:

Non-interventional study

Scope of the study:

Other

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

To perform a study of NVAF patients based on real-world data through the reuse of electronic health records (EHRs)

Main study objective:

The overall objective is to perform a study of NVAF patients based on real-world data through the reuse of electronic health records (EHRs). This approach avoids missing valuable information, and reduces biases normally present in this type of studies.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

APIXABAN

DABIGATRAN ETEXILATE

RIVAROXABAN

EDOXABAN

WARFARIN

ACENOCOUMAROL

Medical condition to be studied

Atrial fibrillation

Additional medical condition(s)

STROKESYSTEMIC EMBOLISMMAJOR AND MINOR BLEEDING EVENTS

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

60000

Study design details

Outcomes

To describe the demographic and clinical characteristics, including comorbidities, for OAC patients who were prescribed apixaban, dabigatran, rivaroxaban, edoxaban, acenocumarol or warfarin, • To describe treatment pathways, and report annual incidence rates of stroke/SE, major and minor bleedings for patients receiving OACs • To compare the rates of stroke/SE,

major and minor bleedings and evaluated comparative rates across various subgroups among NVAF patients receiving OACs • To describe bleeding and stroke-related health care resource utilization in the study populations

Data analysis plan

The methodology of this study is based on SAVANA, a data-driven system based on NLP and big data techniques, designed to analyse unstructured data contained in the electronic medical files. Eligible patients will be assigned to one of the OAC cohort (apixaban, dabigatran, rivaroxaban, edoxaban, warfarin, or acenocumarol). One-to-one propensity score matching (PSM) will be conducted between NOACs and acenocumarol and between the NOACs. As well as overall NOACs versus VKA (acenocumarol and warfarin). Patients will be matched 1:1 in each data set based on the propensity scores generated.

Documents

Study results

B0661131_AFIRMA FINAL STUDY REPORT_13OCT2023-comprimido.pdf (3.97 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 source(s), other

Electronic healthcare records of NVAF patients treated with OACs from the available centers in Spain Spain

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Electronic healthcare records of NVAF patients treated with OACs from the available centers in Spain

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