Non-Interventional, cross-sectional study to describe NOACs management in elderly patients with non-valvular atrial fibrillation (NVAF) in Spain. RE-BELD Study

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Study Finalised

Administrative details

EU PAS number

EUPAS29867

Study ID

42008

DARWIN EU® study

No

Study countries

Spain

Study description

This study has been designed in order to describe the current non-vitamin K antagonist oral anticoagulants (NOACs) management in elderly patients in Spain. It will be conducted in approximately 50 sites in Spain, by investigators from the following specialties: cardiologists, hematologists and geriatricians. It is planned to have a 9-month recruitment period from first site initiated, or until the sample size is achieved. Primary objective: To describe the pattern of usage of NOACs prescribed according to their Summary of Product Characteristics (SmPC), by current NOAC type and dose, in elderly patients (≥75 years-old) with non-valvular atrial fibrillation (NVAF) at the time of the study visit. Secondary objectives: 1. To describe patients characteristics at the time of the study visit by current NOAC type stratified by duration since first NOAC initiation. 2. To describe OAC treatment management since first NOAC initiation until the study visit by duration since first NOAC initiation: previous vitamin K antagonists (VKA) treatment, first NOAC treatment duration, NOAC dose changes, switch between NOACs and reasons for switch, total NOAC treatment duration and additional antiplatelet treatment. 3. To describe the Clinical Frailty Scale grading, CFS, at the time of the study visit, by current NOAC type. 4. To describe first NOAC usage by NOAC type, for primary prevention or secondary prevention, at the time of first NOAC initiation. Further objective: To evaluate the appropriateness of prescribed therapy based on Spanish health authorities recommendations (therapeutic positioning report) and other regional guidelines by NOAC type (if there are enough patients for a NOAC type), at the time of first NOAC initiation. The design of the study impose a single visit to be performed for the informed consent signature and data collection that will coincide with one of those performed by the patients as part of the routine follow-up of their disease.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 50 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Vivencio Barrios

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/05/2019

Actual: 09/05/2019

Study start date

Planned: 16/09/2019

Actual: 09/09/2019

Data analysis start date
Planned: 17/11/2020

Actual: 23/11/2020

Date of final study report
Planned: 16/07/2021

Actual: 13/07/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim España, S.A.

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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe the pattern of usage of NOACs prescribed according to their Summary of Product Characteristics (SmPC), by current NOAC type and dose, in elderly patients (≥75 years-old) with non-valvular atrial fibrillation (NVAF) at the time of the study visit.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Elderly patients (≥75 years-old) with non-valvular atrial fibrillation (NVAF) at the time of the study visit.

Age groups

- 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

500

Study design details

Outcomes

The primary outcome is the pattern of usage of non-vitamin K oral anticoagulants (NOACs) prescribed according to their Summary of Product Characteristics (SmPC), based on the percentage of patients by NOAC type and dose the patient is taking at the time of the study visit. Timeframe to complete data collection for this outcome is one day, the study visit day. Patient’s characteristics at the time of the study visit (by NOAC type) that the patient is taking at the time of the study visit. OAC treatment management (since first NOAC initiation until the study visit date). Clinical Frailty Scale grading (time of

the study visit) by current NOAC type. First NOAC usage by NOAC type, for primary or secondary prevention, at time of first NOAC initiation

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Data analysis plan

Analyses will be performed by Boehringer Ingelheim’s designees. In this non-interventional study, retrospective data from medical charts and data at the study visit will be collected for non-valvular AF patients. Once the study has been completed and all data from the last patient have been recorded, the database will be closed and statistical analysis will be performed. The proposed methods for statistical analysis presented below are a summary of the methods that will be applied in the study to analyze the data collected and to answer the study objectives. Since the study is descriptive, the variables included in the study objectives will be summarized overall and by factors of interest. All results will be summarized with measures of central tendency (mean and median), variability/dispersion (standard deviation and interquartile ranges), absolute and relative frequencies, and ranges. A Statistical Analysis Plan will be prepared.

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)

Electronic healthcare records (EHR)

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