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

First published: 24/07/2017

Last updated: 31/03/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS19987

Study ID

33195

DARWIN EU® study

No

Study countries

☐ Spain

Study description

This is an observational, multicentre, cross-sectional study based on newly collected data that will be conducted in cardiology departments, in at least 102 centers in Spain.This study observes the use of new oral anticoagulants (NOACs) in patients with a heart rhythm disorder in Spain.The primary objective of the study is to describe the usage of NOACs in patients with NVAF, in the hospital setting, based on the baseline characteristics at the time of first NOAC initiation.Secondary objectives:- To evaluate the appropriateness of prescribed therapy based on Spanish health authorities' recommendations (positioning therapeutic report)- To describe NOAC treatment management.- To describe the patient's knowledge about anticoagulant treatment, independent of NOAC type.Further objectives:- To evaluate the appropriateness of prescribed therapy based on Spanish health authorities' recommendations (positioning therapeutic report) per NOAC type and by autonomous community.

Study status

Finalised

Research institutions and networks

Institutions

Hospital Clínico Universitario de Santiago de Compostela

Multiple centres: 102 centres are involved in the study

Contact details

Study institution contact

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Primary lead investigator

José Ramón González Juanatey

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2017

Actual: 01/06/2017

Study start date

Planned: 27/11/2017

Actual: 11/12/2017

Data analysis start date

Planned: 01/04/2019

Date of final study report

Planned: 24/01/2020

Actual: 09/01/2020

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:

The primary objective of the study is to describe the usage of NOACs in patients with NVAF, in the hospital setting, based on the baseline characteristics at the time of first NOAC initiation.

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

Patients, mainly from the hospital setting, were included in the study if all of the following criteria were met:

1. The patient was willing and provided written informed consent to participate in this study
2. The patient was at least 18 years of age
3. The patient had a diagnosis of non-valvular atrial fibrillation (NVAF)

4. The patient was on treatment with NOAC according to its approved local Summary of Product Characteristics (SmPC) and had initiated his first NOAC starting from November 2016

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

Atrial fibrillation patients

Estimated number of subjects

1000

Study design details

Outcomes

The primary outcome is the usage of NOACs, in patients with NVAF, in the hospital setting, based on the baseline characteristics at the time of first NOAC initiation. Baseline (at time of first NOAC initiation) variables will be analysed descriptively by NOAC type. Treatment groups will be defined according to first NOAC prescribed. The time frame for assessing this outcome is 7 months. - Appropriateness of NOAC prescription based on national recommendations

(positioning therapeutic report) is planned.- NOAC treatment management.- Patient’s knowledge about his condition.

Data analysis plan

Analyses will be performed by Boehringer Ingelheim’s designees. The analysis population will consist of all eligible patients (i.e. all patients fulfilling all inclusion criteria and no exclusion criteria). If patients have missing values for an outcome, those patients will be excluded for that outcome’s analysis.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.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 andinterquartile ranges), absolute and relative frequencies, and ranges.

Documents

Study results

RE-CONOCE-clinical-study-report-synopsis.pdf (1.04 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)

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

Unknown