Treatment Pattern of NOACs (non-vitamin K oral anticoagulants) in Outpatient Users in Colombian Databases - TREND Colombia

First published: 13/03/2018

Last updated: 04/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS23099

Study ID

34957

DARWIN EU® study

No

Study countries

☐ Colombia

Study description

This population-based descriptive study will characterize first-time users of three NOACs (rivaroxaban, dabigatran and apixaban) in prevention of stroke in non-valvular atrial fibrillation (SPAF) patients and will assess the patterns of drug utilization in routine general practice in Colombia

Study status

Finalised

Research institutions and networks

Institutions

Fundación Centro Español de Investigación Farmacoepidemiológica (CEIFE)

Spain

First published: 15/03/2010

Last updated: 15/02/2024

Institution | Not-for-profit | ENCePP partner

Networks

Grupo de Investigación en Farmacoepidemiológica y Farmacovigilancia, Faculty of Health Sciences, Universidad Tecnológica de Pereira, Colombia

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Luis Alberto García Rodríguez

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/01/2018

Actual: 22/02/2018

Study start date

Planned: 28/02/2018

Actual: 28/02/2018

Date of final study report

Planned: 31/12/2018

Actual: 07/05/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

20104_TREND Colombia Protocol_ENCEPP.pdf(1010.54 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

This population-based descriptive study will characterize first-time users of three non-vitamin k antagonists oral anticoagulants (rivaroxaban, dabigatran and apixaban) in non-valvular atrial fibrillation patients and will assess the patterns of drug utilization in routine general practice in Colombia.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AF01) rivaroxaban

rivaroxaban

(B01AF02) apixaban

apixaban

Medical condition to be studied

Thrombotic stroke

Population studied

Short description of the study population

All patients aged ≥18 years with a diagnosis of Non valvular Atrial Fibrillation (NVAF) and with at least 1 year of enrollment with their primary care physician (PCP) in the Audifarma S.A database and with 1 year since their first recorded health contact r were eligible for inclusion. Three mutually exclusive cohorts of first-time users of a Non-vitamin K antagonist Oral Anticoagulants (NOAC) (rivaroxaban, apixaban or dabigatran) with the date of first prescription the NOAC (index drug) being the index date, and followed all patients for at least 1 year.

Inclusion Criteria

1. First prescription of NOACs (rivaroxaban, dabigatran and apixaban) in the outpatient setting.
2. NVAF Patients
3. aged ≥18 years
4. at least one year of enrollment in the Audifarma database
5. one year since first encounter with healthcare provider will be included in the study.

Exclusion criteria

1. Patients with any record of index drug prescription prior to the enrolment period.
2. Patients who qualify as members of more than one cohort study on the same day.

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

Non-valvular atrial fibrillation (NVAF) patients

Estimated number of subjects

15000

Study design details

Outcomes

• Baseline patient characteristics of SPAF patients in Colombia prescribed any of the three NOACs (rivaroxaban, dabigatran and apixaban) for the first time for stroke prevention• Outpatient patterns (daily dose, dose posology, naïve status and treatment duration) of rivaroxaban, dabigatran and apixaban use in SPAF patients, • Time-trends in the characteristics of first-time use of NOACs in SPAF patients. The primary endpoints like patient characteristics, medical history, medication history, characteristics of index prescription, stratified per year (wherever possible).

Data analysis plan

The analysis will be based on descriptive statistics: frequencies and percentages will be calculated to the variables of interests, continuous and count variables will be described using mean (±standard deviation), proportions, median (quartiles) and minimum and maximum values. 95% confidence intervals will be computed for descriptive variables.

Documents

Study results

20104_EU-PAS_Abstract_2019-07-29_Redacted.pdf(72.45 KB)

20104_EU-PAS_Abstract_Redacted_2020-03-25.pdf(72.5 KB)

Study report

20104_EU-PAS_study report_2019-07-29_Redacted.pdf(609.99 KB)

20104_NOACs in Colombia_Study Report_amendments 6 Jan 2020_Redacted.pdf (647.42 KB)

Study, other information

20104_NOACs in Colombia_Study Report_amendments 6 Jan 2020_Redacted.pdf (647.42 KB)

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Other

Data sources (types), other

Audifarma S.A. Colombia

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