# 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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**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

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**Study start date**

Planned: 28/02/2018

Actual: 28/02/2018

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**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)

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**Special population of interest**

Other

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**Special population of interest, other**

Non-valvular atrial fibrillation (NVAF) patients

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**Estimated number of subjects**

15.000

## 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).

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**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)

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**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

## 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)**

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