# Apixaban drug utilization study in Stroke prevention in atrial fibrillation (SPAF)

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# Administrative details

EU PAS number	
EUPAS13180	
Study ID	
28119	
DARWIN EU® study	
-	
No	
Study countries	
Spain	
Spain	

#### **Study status**

Finalised

Research institutions and networks

## **Institutions**



## Contact details

#### **Study institution contact**

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### **Primary lead investigator**

Morros Pedrós Rosa

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 11/11/2015 Actual: 11/11/2015

#### Study start date

Planned: 29/04/2016 Actual: 01/06/2016

#### Data analysis start date

Planned: 01/07/2016 Actual: 05/07/2016

#### Date of interim report, if expected

Planned: 01/11/2016 Actual: 30/11/2016

#### **Date of final study report**

Planned: 30/12/2016 Actual: 08/03/2017

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Pfizer

## Study protocol

Apixaban B0661076 15-Feb.pdf (385.13 KB)

# 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	
Human medicinal product	
Study type:	
Non-interventional study	
Scope of the study:	
Drug utilisation	
Data collection methods:	

## Main study objective:

The primary research question is to evaluate the apixaban utilization according to the approved SPAF indication and recommendations by EMA.In addition a

comparison with a cohort of NVAF patients treated with VKA, dabigatran and rivaroxaban for the SPAF indication will also be performed.

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

#### **Anatomical Therapeutic Chemical (ATC) code**

(B01A) ANTITHROMBOTIC AGENTS
ANTITHROMBOTIC AGENTS

#### Medical condition to be studied

Atrial fibrillation

# Population studied

#### Short description of the study population

Individuals diagnosed with non-valvular atrial fibrillation (NVAF) from source population who had a new prescription for apixaban, VKA (warfarin or acenocoumarol), dabigatran or rivaroraban from August 2013 until December 2015 and a previously recorded diagnostic of NVAF.

#### 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**

20000

# Study design details

#### **Outcomes**

To characterize patients using apixaban according to demographics, comorbidity, risk of thromboembolic events (CHADS2 and CHA2DS2-Vasc scores), risk of bleeding events (HAS-BLED score), comedications and compare it with the profile of patients treated with VKA, dabigatran and rivaroxaban. Describe the level of appropriate usage according to the posology recommended in the apixaban SmPCDescribe the potential interactions with other drugs prescribed concomintatly according with the SmPC recommendationsEstimate the level of apixaban adherence by the medication possession ratio (MPR) and discontinuation rates and compare it with VKA, dabigatran and rivaroxabanTo analyze INR

#### **Data analysis plan**

The use and patterns of use of Apixaban and VKA will be summarised by the total number of users, prescriptions, and number of DDDs, and by the number of users according to daily dose and duration of use. Characteristics of users, comorbidity, comedications, use of interacting drugs will be described as number and percentage of patients with each condition. The number and percentage of all variables will be calculated by apixaban VKA, dabigatran and rivaroxaban group. In general, frequencies will be used to describe the study sample characteristics and characteristics of each category group. Chi-square tests and ANOVA will be utilized to compare categorical and continuous variables, respectively, across the category groups.

## **Documents**

#### Study results

NIS\_Report\_APIXABAN Summary\_FINAL 08032017.pdf (787.47 KB)

#### **Study publications**

Gomez-Lumbreras A, Cortes J, Giner-Soriano M, Quijada-Manuitt MA, Morros R. Cha...

Gómez-Lumbreras A, Giner-Soriano M, Quijada-Manuitt MA, Cortés J, Morros R. Pós...

# 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)

The Information System for Research in Primary Care (SIDIAP)

#### 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