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

First published: 18/04/2016

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/28119

EU PAS number

EUPAS13180

Study ID

28119

DARWIN EU® study

No

Study countries

☐ Spain

Study status

Finalised

Research institutions and networks

Institutions

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/02/2024

Institution | **Educational Institution** | **Laboratory/Research/Testing facility** | **Not-for-profit** | **ENCePP partner**

Contact details

Study institution contact

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Study 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:

Secondary use of data

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

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