Pattern of use of Direct Oral Anticoagulants in Non-valvular Atrial Fibrillation patients in UK general practices

First published: 14/04/2017

Last updated: 04/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/34784

EU PAS number

EUPAS18521

Study ID

34784

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Many people who suffer from irregular heartbeats (atrial fibrillation) which might cause stroke, need to take blood thinners to prevent it. It is important to prescribe the correct dose of blood thinners to the right patients to ensure the treatment works however avoiding complications. In the recent years, new blood thinners have been available, they require less laboratory tests and fewer visits to a doctor compared to older therapies. This study will look at how the general practitioners in the UK prescribe blood thinners according to the instructions given by the product manufacturer. We will use primary care data that is routinely collected by the general practitioners about their patients but without any possibility to identify individual patients. The results will help us to understand the magnitude of deviation from instructions in order to ensure that the patients benefit from the treatment.

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

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: 30/01/2017

Actual: 30/01/2017

Study start date

Planned: 15/05/2017

Actual: 15/05/2017

Data analysis start date

Planned: 15/05/2017

Actual: 15/05/2017

Date of final study report

Planned: 31/01/2019

Actual: 21/05/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

THIN-CPRD Protocol_NOAC PASS_02032017_PRC_Clean.pdf(1.04 MB)

THIN-CPRD Protocol_NOAC PASS_02032017_PRC_Final.pdf(2.48 MB)

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 objective of the study is to characterize first-time users of three DOACs in NVAF patients for stroke prevention including those renal impaired and to assess patterns of drug utilization in routine general practice in the UK

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

Among the source population resulting from the combination of THIN and CPRD databases, study will ascertain three separate cohorts of first-time users of rivaroxaban, apixaban and dabigatran using the date of first prescription (index date) of the respective drug (index drug).

This study will apply a new-users (initiators) design. New users are individuals starting a study medication for the first time ever recorded in the database. Yet, they may have used the other study medications before index date and therefore classified as non-naïve. Newusers without any history of any oral anticoagulant would be classified as naïve. All patients aged 18 and above and who have been enrolled in the databases for at least 1 year and had their first prescription recorded in the databases at least 1 year ago will be included in source population. A patient will be considered eligible to enter a study cohort as a first-time user of one the study drugs when he or she has a first prescription of the drug recorded during the enrolment period.

Patients who have any record of being prescribed their index drug prior to the enrolment period or who qualify as members of more than one cohort on the same day, will be excluded. If a patient qualifies as first-time user of more than one study drug during the enrolment period, with different index dates, she/he will be assigned to the cohort of study drug first prescribed during the enrolment period, with the date of this prescription being the index date. (eg

mutually exclusive cohorts).

Patients with NVAF defined as:-

Patients with a record of Atrial fibrillation (AF) any time prior index date or within the 2 weeks after the index date, and free of valvular replacement or mitral stenosis prior to index date or 2 weeks after index-date.

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

30000

Study design details

Outcomes

1.Demographic Characteristics2.Risk factor categories3.Previous medical history4.Previous medication history5.Previous use of VKA6.Concurrent co-medication7.Daily dose8.Dose posology9.Naive status and Non-naive status10.Treatment Duration, Time-trends

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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 intercals will be computed for descriptive varaibles.

Documents

Study results

Study 19330_EU PAS Abstract_Redacted_2020-03-20.pdf(633.3 KB)

Study report

Study 19330_EU PASS_Redacted_2020-03-20.pdf(5.19 MB)

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Clinical Practice Research Datalink

Data sources (types)

Drug dispensing/prescription data

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

No