Adherence, persistence and switching patterns – once- and twice-daily direct oral anticoagulants (QD versus BID DOACs)

First published: 21/02/2019

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS28224

Study ID

32840

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ Italy
- ☐ Netherlands

Study status

Finalised

Research institutions and networks

Institutions

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

First published: 07/01/2022

Last updated: 24/07/2024

Institution | **Laboratory/Research/Testing facility** | **ENCePP partner**

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

Last updated: 26/02/2024

Institution | **Not-for-profit** | **ENCePP partner**

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

First published: 07/01/2022

Last updated: 24/07/2024

Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ron Herings

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/10/2018

Actual: 17/10/2018

Study start date

Planned: 02/01/2019

Actual: 02/01/2019

Date of final study report

Planned: 29/11/2019

Actual: 19/12/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Daiichi Sankyo Europe GmbH

Study protocol

PHARMO - Protocol QD vs BID DOACs -15jan2019.pdf(530.51 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 objectives of this study are to:• determine the relationship between adherence and QD vs. BID• determine the relationship between persistence and QD vs. BID• determine the relationship between adherence and switchers vs. non-switchers• determine the relationship between persistence and switchers vs. non-switchers• compare switching patterns for QD and BID

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AF) Direct factor Xa inhibitors

Direct factor Xa inhibitors

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Patients using direct oral anticoagulants (DOACs) for the treatment of Atrial fibrillation (AF).

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

130000

Study design details

Outcomes

Adherence and persistence

Data analysis plan

Adherence to treatment will be defined based on the proportion of days covered (PDC) during the exposure period. Persistence with treatment will be defined as the time from index date to treatment discontinuation and will be based on DOAC treatment episodes.Switching patterns will be assessed from the day after index date until the end of follow-up based on DOAC treatment episodes. This will be defined as either the occurrence of a dosage regimen switch or a BID/QD cluster switch (i.e. to another DOAC with the same dosage regimen).

Documents

Study results

PHARMO - Report QD vs BID DOACs - June2019.pdf(1.06 MB)

Data management

Data sources

Data source(s)

PHARMO Data Network

German Pharmacoepidemiological Research Database

ARS Toscana

Data source(s), other

PHARMO Data Network, GePaRD, ARS

Data sources (types)

Administrative healthcare records (e.g., claims)

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