# 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 status** 



# Administrative details

EU PAS number	
EUPAS28224	
Study ID	
32840	
DARWIN EU® study	
No	
Study countries	
Germany	
☐ Italy	
Netherlands	

# 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
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

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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

## **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)

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