Comparative Effectiveness and Safety of Direct Oral Anticoagulants in Patients with Nonvalvular Atrial Fibrillation in the UK

First published: 10/01/2022

Last updated: 20/10/2022

Study Planned

Administrative details

EU PAS number

EUPAS45073

Study ID

49469

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This study aims to evaluate the incidence of stroke and other outcomes in association with direct oral anticoagulants (DOACs) as compared to each other (i.e., direct comparisons) among patients with nonvalvular atrial fibrillation (AFib) in the UK. Individual DOACs of interest include apixaban, rivaroxaban, edoxaban, and dabigatran.

Study status

Planned

Research institutions and networks

Institutions

Aetion

Spain

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Institution | Other | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ayad Ali

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 08/06/2021

Study start date
Planned: 01/09/2021

Date of final study report
Planned: 28/02/2022

Sources of funding

- Other

More details on funding

Aetion

Study protocol

AFib Protocol_07JAN22_FINAL.pdf (403.09 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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

This study aims to evaluate the incidence of stroke and other outcomes in association with direct oral anticoagulants (DOACs) as compared to each other (i.e. direct comparisons) among patients with nonvalvular atrial fibrillation (AFib) in the UK. Individual DOACs of interest include apixaban, rivaroxaban, edoxaban, and dabigatran.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AF02) apixaban

apixaban

(B01AF01) rivaroxaban

rivaroxaban

(B01AF03) edoxaban

edoxaban

(B01AE07) dabigatran etexilate

dabigatran etexilate

Medical condition to be studied

Atrial fibrillation

Population studied

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)

Estimated number of subjects

13.991

Study design details

Outcomes

The primary objective is to: Estimate the incidence rates and evaluate the association of stroke (ischemic or hemorrhagic) for patients with nonvalvular AFib who initiated apixaban compared to rivaroxaban, The secondary objectives are to: Compare the incidence rates of stroke for patients who initiated: apixaban compared to edoxaban, dabigatran, and DOACs class, rivaroxaban compared to edoxaban, dabigatran, and DOACs class, edoxaban compared to DOACs class, dabigatran compared to DOACs class, Compare the incidence rates of secondary outcomes for the each head to head comparison.

Data analysis plan

In each comparison cohort, propensity score matching between exposure groups will be performed using 1:1 nearest neighbor matching without replacement with a maximum matching caliper of 0.01. In addition to graphical depictions of propensity score distributions, the absolute standardized differences (ASD) in proportions and means of baseline characteristics will be estimated to examine comparability of exposure groups. Cox proportional hazards regression (outcomes model) will be used to estimate hazard ratios and 95% CI for each outcome after propensity score matching. The incidence of stroke and secondary outcomes will be compared between individual DOACs in primary and secondary comparisons as mutually exclusive cohorts. High-dimensional propensity score (HdPS) analysis will be used as a sensitivity analysis to estimate the association between treatment with DOACs and the primary outcome of stroke.

Documents

Study publications

Jaksa A, Gibbs L, Kent S, Rowark S, Duffield S, Sharma M, Kincaid L, Ali AK, Pa…

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)

THIN® (The Health Improvement Network®)

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

No