# 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

**First published:** 24/11/2022

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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

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**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

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**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)

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**Estimated number of subjects**

13991

## 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.

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**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…

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# 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