# A comparison of the effectiveness and safety of direct oral anticoagulants versus warfarin in older patients with atrial fibrillation using the Clinical Practice Research Datalink

**First published:** 14/03/2021

**Last updated:** 02/04/2024

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS40058

**Study ID**

40720

**DARWIN EU® study**

No

**Study countries**

United Kingdom

**Study description**

The aims of this study are to compare direct oral anticoagulants (DOACs) with warfarin in patients aged ≥ 75 years in the United Kingdom (UK) where they are prescribed for stroke prevention in atrial fibrillation (AF): 1. To compare effectiveness and safety outcomes in patients prescribed DOACs to similar patients started on warfarin prior to DOACs being licensed for use. 2. To compare effectiveness and safety outcomes in patients prescribed DOACs to similar patients started on warfarin after the DOACs were licensed for use. 3. To establish if switching between warfarin and DOACs affects safety or effectiveness outcomes 4. To determine whether safety outcomes differ between warfarin and DOACs in advanced age, for patients with low body weight (<60kg), frailty, dementia or a history of falls

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### University of Bath

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Institution

# Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Mitchell Anneka

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 18/09/2017

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**Study start date**

Planned: 19/03/2021

Actual: 03/04/2021

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**Date of final study report**

Planned: 31/05/2021

## Sources of funding

- Non-for-profit organisation (e.g. charity)

## More details on funding

The Dunhill Medical Trust

## 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:**

To compare the safety and effectiveness of warfarin compared with direct oral anticoagulants when prescribed for stroke prevention in patients aged 75 and over with atrial fibrillation.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Study drug International non-proprietary name (INN) or common name**

WARFARIN

DABIGATRAN

RIVAROXABAN

APIXABAN

EDOXABAN

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**Medical condition to be studied**

Atrial fibrillation

# Population studied

**Age groups**

- Adults (75 to < 85 years)
- Adults (85 years and over)

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**Estimated number of subjects**

36.000

# Study design details

**Outcomes**

Primary effectiveness outcome: Stroke Primary safety outcome: Major bleeding, Secondary safety outcomes: clinically relevant non-major bleeding, intracranial haemorrhage, gastrointestinal haemorrhage, myocardial infarction, and all cause mortality.

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**Data analysis plan**

Baseline characteristics will be reported for each group as percentages, means (standard deviation) or medians (interquartile range). G-estimation will be used to compare the failure time with warfarin and DOACs to each of the primary and secondary outcomes individually . The DOAC group will be compared to both a historical and contemporary warfarin group. Apixaban and rivaroxaban will also be compared to both warfarin groups separately.

# 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)**

Clinical Practice Research Datalink

**Data source(s), other**

CPRD

**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