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

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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

Study start date

Planned: 19/03/2021

Actual: 03/04/2021

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

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:

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

Medical condition to be studied

Atrial fibrillation

Population studied

Age groups

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

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.

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

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