Utilisation of oral anticoagulants in older people with atrial fibrillation in UK general practice

First published: 27/06/2019

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Study Ongoing

Administrative details

EU PAS number

EUPAS29923

Study ID

39711

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Atrial fibrillation (AF) is a heart condition that increases the risk of stroke. Blood thinning tablets known as oral anticoagulants (OACs) help to reduce the risk of stroke and guidelines recommend that OACs are prescribed to people with AF who also have other risk factors for stroke such as heart failure, high blood pressure or diabetes. Vitamin K antagonists (VKAs), such as warfarin, were the only OACs available. VKAs are difficult to manage as they require frequent blood tests and regular dose changes, they also interact with lots of other medicines and food. Historically, VKAs have been under-used in older people due to concerns about patients managing the complex dosing schedule if they have cognitive impairment, and also the risk of brain bleeds if they fall. Direct oral anticoagulants (DOACs) were introduced as an alternative to VKAs in 2008 but were not licensed for stroke prevention in AF until 2011. It is not known whether the introduction of DOACs has changed the rates of OAC prescribing for older people (aged 75 years and over) or how patient demographics, other medical conditions and concomitant prescribing affect the choice of OAC prescribed in UK general practice. The objectives of the study are: 1. To describe changes in the point prevalence and incidence of OAC prescribing by year prior to the introduction of DOACs (2003-2007), between the introduction of DOACs and the time they were recommended as an option by the National Institute for Health and Clinical Care Excellence (NICE) for stroke prevention in AF (2008-2012), and following publication of NICE technology appraisals recommending DOACs (2013-2017). 2. To describe switching between OACs during the study period. 3. To compare the characteristics of patients with AF who were newly started on OACs during each period described in objective 1, to those not prescribed an OAC in the same period. 4. To describe persistence with DOACs compared with warfarin.

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: 18/09/2018

Study start date

Actual: 01/05/2019

Data analysis start date
Planned: 30/07/2019

Actual: 31/07/2019

Date of final study report
Planned: 31/03/2021

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:

Drug utilisation

Main study objective:

1) To describe changes in the point prevalence and incidence of OAC prescribing by year2) To describe switching between OACs during the study period3) To compare the characteristics of patients with AF who were newly started on OACs tothose who weren't during 3 study periods: 2003-2007, 2008-2012, 2013-2017.4) To describe persistence with DOACs compared with warfarin

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AF01) rivaroxaban

rivaroxaban

(B01AF02) apixaban

apixaban

(B01AF03) edoxaban

edoxaban

(B01AA03) warfarin

warfarin

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

168.000

Study design details

Data analysis plan

Point prevalence of OAC prescribing will be calculated at the midpoint of each year.The incidence of OAC prescribing will be calculated overall and for each specific OAC.Everyone in the cohort will be considered 'at risk' until the time they receive their first OAC prescription. For the person-time at risk calculation the denominator will be truncated at the date of their first OAC prescription. Incidence will be stratified by age (75-84 and 85+) and sex. The number and percentage of patients switching OAC will be calculated. The number of patients with multiple switches and details of the switches will be described. Average time to switch will be reported. Demographics, characteristics, co-morbidities and concomitant medications will be reported for each period in the no OAC, DOAC and warfarin groups.Duration of prescribing of DOACs will be compared to warfarin using Cox-proportional hazards, stratified by DOAC and adjusted for age and other important covariates, if feasible.

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