Finnish AntiCoagulation in Atrial Fibrillation (FinACAF)

First published: 23/05/2019

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS29845

Study ID

39871

DARWIN EU® study

No

Study countries

Finland

Study status

Finalised

Research institutions and networks

Institutions

Helsinki University Hospital (HYKS)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Turku University Hospital Turku, Finland, Aalto University Espoo, Finland

Contact details

Study institution contact

Mika Lehto mika.lehto@hus.fi

Study contact

mika.lehto@hus.fi

Primary lead investigator

Mika Lehto

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 24/12/2018

Actual: 01/01/2019

Study start date
Planned: 02/09/2019

Actual: 02/09/2019

Data analysis start date
Planned: 01/01/2020

Date of final study report
Planned: 03/08/2020

Actual: 10/03/2021

Sources of funding

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

More details on funding

EVO HUS, Koskelo foundation, Finnish foundation for cardiovascular research

Study protocol

Tutkimussuunnitelma_FinACAF_21052015.pdf (265.82 KB)

Tutkimussuunnitelma_FinACAF_02032021.pdf (326.25 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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To investigate risk of stroke, systemic thromboembolism, bleeding events and myocardial infarction among AF patients in relation to different OAC treatments including warfarin treatment with the data of different TTR levels compared also with patients without any OAC treatment.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AA03) warfarin

warfarin

(B01AF) Direct factor Xa inhibitors

Direct factor Xa inhibitors

(B01AE07) dabigatran etexilate

dabigatran etexilate

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

The study cohort consists of patients from six hospital district areas having a diagnosis of AF. The included geographically defined hospital districts are Northern Ostrobotnia, Northern Savonia, Central Finland, Pirkanmaa, Southwest, and Helsinki and Uusimaa.

Inclusion Criteria
Patients fulfilling the following criteria are included in the study:
• patient has an International Classification of Diseases (ICD-10 version 10) diagnosis code I48 for AF during 1.1.2004-30.06.2018 in any of the used registries

Exclusion Criteria
• Patients with permanent residence in Finland less than 12 months prior to index date.
• Patients with age below 18 years at index date.

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)

Special population of interest

Other

Special population of interest, other

Atrial fibrillation patients

Estimated number of subjects

180.000

Study design details

Outcomes

Stroke, Other systemic thromboembolic events excluding stroke, Myocardial infarction, Bleeding events, Mortality (all-cause), Mortality (stroke), Mortality (myocardial infarction), Mortality (systemic thromboembolic events excluding stroke), Mortality (bleeding events), Anemia, renal impairment, use of blood products

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Data analysis plan

Stratified incidence rates with 95% CIs will be estimated for each endpoint within the strata of the time in therapeutic INR range (TTR) categories, and other covariates. The crude and adjusted hazard ratio (HR) estimates with 95% CIs and P-values will be estimated within the TTR categories and NOACs and patients without any anticoagulation using the conventional Cox’s proportional hazards model adjusting for other covariates

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 sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Drug registry

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prescription event monitoring, National Reimbursement Register, Finnish Care Register, National Causes of Death Register, Finnish Cancer Registry. National Prescription Register, Laboratory databases of Finnish Hospital districts, Population Register, Social HILMO, Finnish Tax Register, The Finnish Register of Completed Education and Degrees

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