Plasma concentrations of direct oral anticoagulants in patients with atrial fibrillation.

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Study Ongoing

Administrative details

EU PAS number

EUPAS105053

Study ID

105054

DARWIN EU® study

No

Study countries

Norway

Study status

Ongoing

Research institutions and networks

Institutions

St. Olav's University Hospital

First published: 01/02/2024

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Institution

Department of Clinical Pharmacology

Contact details

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Study contact

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Primary lead investigator

Olav Spigset

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/01/2021

Actual: 14/01/2021

Study start date
Planned: 19/04/2021

Actual: 19/04/2021

Date of final study report
Planned: 31/12/2024

Sources of funding

- Other

More details on funding

St Olav University hospital

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:

Other

If ‘other’, further details on the scope of the study

Drug adherence and pharmacokinetics

Main study objective:

To investigate the variation in DOAC serum levels in patients with expected optimal adherence and how adherence to DOACs influences this variation.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

APIXABAN

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)

Estimated number of subjects

200

Study design details

Outcomes

To investigate the variation in DOAC serum levels in patients with expected optimal adherence and how adherence to DOACs influences this variation. Relationship between MMAS-8 scores and concentration dose ratios (CDRs) of DOACs just before ablation, effect of age, sex, renal function on CDRs just before ablation, relationship between MMAS-8 scores and CDRs 3 months after ablation, effect of age, sex, renal function on CDRs 3 months after ablation, relationship between MMAS-8 scores just before ablation and 3 months after ablation

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Data analysis plan

- relationship between MMAS-8 scores and concentration dose ratios (CDRs) of DOACs just before ablation - effect of age, sex, renal function on CDRs just before ablation - relationship between MMAS-8 scores and CDRs 3 months after ablation - effect of age, sex, renal function on CDRs 3 months after ablation - relationship between MMAS-8 scores just before ablation and 3 months after ablation

Data management

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)

Other

Data sources (types), other

Patients to undergo cardiac ablation will be included. DOAC plasma concentrations will be drawn one week before the procedure and again at two, six, and ten weeks after the procedure. MMAS- adherence scale will be answered by each patient at two points in time, one week before the procedure as well as 11 weeks after the procedure.

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