

Treatment and outcomes among patients with atrial fibrillation and acute coronary syndrome in Sweden

First published: 29/03/2018

Last updated: 01/04/2024

Study

Finalised

Administrative details

EU PAS number

EUPAS23407

Study ID

26832

DARWIN EU® study

No

Study countries

 Sweden

Study description

Many people who suffer from irregular heartbeats (atrial fibrillation) which might cause stroke, need to take blood thinners to prevent it. However, people with atrial fibrillation are also at increased risk of acute myocardial infarction or unstable angina pectoris (another heart condition marked by a chest pain, comprising so-called acute coronary syndrome for which another type of treatment that prevents blood from clotting (antiplatelet treatment) is indicated. In particular if such patients undergo percutaneous coronary intervention, a procedure aimed to open up diseased blood vessels and hence to treat acute coronary syndrome, this treatment is needed. If a patient takes several anti-clotting blood drugs, the risk of bleeding is high. The number of possible drug combinations and treatment durations is large. This study will help us to understand which anti-clotting drug combinations are prescribed in real life among patients with atrial fibrillation and acute coronary syndrome, how effective and safe they are for patients. The study will look into the data that are already available in several very large Swedish databases which contain information needed for the research

Study status

Finalised

Research institutions and networks

Institutions

[Friberg Research AB, Karolinska Institute](#)

 Sweden

First published: 19/03/2014

Last updated: 20/08/2024

Institution

Educational Institution

Hospital/Clinic/Other health care facility

Laboratory/Research/Testing facility

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Leif Friberg

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/06/2017

Actual: 09/06/2017

Study start date

Planned: 01/12/2011

Actual: 01/12/2011

Date of final study report

Planned: 15/06/2018

Actual: 01/06/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

[19562_Protocol_Sweden_ACS-AF_Encepp.pdf](#) (689.19 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To describe prescription patterns of antithrombotic drugs in real life among patients with atrial fibrillation and acute coronary syndrome in Sweden, and to study safety and effectiveness endpoints related to the most commonly administered treatment regimens

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AF01) rivaroxaban

rivaroxaban

(B01AF02) apixaban

apixaban

Medical condition to be studied

Atrial fibrillation

Acute coronary syndrome

Population studied

Short description of the study population

Patients with Atrial fibrillation (AF) and Acute coronary syndrome (ACS) who did not undergo Percutaneous Coronary Intervention (PCI), who underwent PCI without stent implantation (NOMESCO code FNG00-96 except FNG05), who underwent PCI with stent implantation (NOMESCO code FNG05).

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 and Acute coronary syndrome patients

Estimated number of subjects

Study design details

Outcomes

Composition and frequency of treatment regimens (NOTE: please refer to <https://clinicaltrials.gov/> for description of further primary outcomes)

Data analysis plan

The analysis will be of descriptive nature and will be conducted for subgroups of patients: (1) those who did not undergo PCI (“no PCI”), (2) who underwent PCI without stent implant. Frequencies and percentages will be calculated to the variables of interests, continuous and count variables will be described using mean (\pm SD), proportions, median (quartiles) and minimum and maximum values. 95% confidence intervals will be computed for descriptive variables. The main analyses will be made similarly to the intention to treatment principle where patients are grouped according to treatment at baseline not accounting for changes during follow up. Unadjusted event rates according to a regimen and an outcome will be presented in table format as well as displayed as Kaplan Meier graphs. Multivariable Cox regression with adjustments for cofactors will be made pairwise for the major treatment pathways

Documents

Study results

[19562_EU-PAS_Abstract.pdf](#) (64.1 KB)

Study report

[19562_Study Report.pdf](#) (5.86 MB)

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)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data sources (types)

[Drug dispensing/prescription data](#)

[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

Unknown