STUDY ON THE PREVENTION OF CARDIOVASCULAR EVENTS BY ANTIPLATELET AGENTS AFTER ACUTE CORONARY SYNDROME (AReMIS)

First published: 04/03/2014

Last updated: 01/02/2017

Study Ongoing

Administrative details

EU PAS number

EUPAS5905

Study ID

17589

DARWIN EU® study

No

Study countries

France

Study description

The Primary objective of this study is to compare the relative risk of new myocardial infarction (MI) or cardiac death in patients with a history of acute coronary syndrome ('ACS': unstable angina or myocardial infarction), using ticagrelor, clopidogrel or prasugrel (if applicable) or none of these treatments, where aspirin is considered a covariate. Secondary objectives include the estimation of the incidence rates among patients with a history of acute coronary syndrome (unstable angina or myocardial infarction), exposed to the use of ticagrelor, clopidogrel, prasugrel, or none of these treatments, of the following events: recurrent myocardial infarction (rMI), stroke, major bleeding (requiring hospitalization) and non-major and death, to describe patterns of use for ticagrelor and other antiplatelet agents (indication, substitutions, etc.), including the discontinuation of treatment and reasons, and to study the influence of risk factors on the risk of cardiovascular events in participating patients and assess how these factors interact with ticagrelor and other antiplatelet drugs.The study design is a general cohort of patients with acute coronary syndrome (ACS) followed for 12 months for the occurrences of interest. A case-cohort analysis will compare drug exposure between patients who have had an occurrence of interest to those who did not (population-time with no event). Medical information at baseline is entered by cardiologists in the PGRx system. Drug exposure is obtained from cardiologists and patients through standardized and validated telephone interviews. Events of interest are examined by an adjudication committee. A total of 3,750 patients with ACS will be needed to achieve a power of 80% to detect an Odds ration inferior to 0.8 for the comparison ticagrelor to the each of clopidogrel and prasugrel, assuming approximately equal exposure in the population of interest.

Study status

Ongoing

Research institutions and networks

Institutions

Real World Studies, LA-SER Research

France

United Kingdom

First published: 23/03/2012

Last updated: 23/03/2012

Institution | Outdated | Other | ENCePP partner

Networks

PGRx®

France

United Kingdom

First published: 30/03/2010

Last updated: 17/01/2012

Network | Outdated | ENCePP partner

Contact details

Study institution contact

Lamiae Grimaldi lamiae.grimaldi@la-ser.com

Study contact

lamiae.grimaldi@la-ser.com

Primary lead investigator

Lamiae Grimaldi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/11/2012

Study start date

Planned: 01/09/2013

Actual: 04/10/2013

Date of final study report

Planned: 20/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astra-Zeneca

Regulatory

Was the study required by a regulatory body?

Yes

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:

The Primary objective of this study is to compare the relative risk of new myocardial infarction (MI) or cardiac death in patients with a history of acute coronary syndrome ('ACS': unstable angina or myocardial infarction), using ticagrelor, clopidogrel or prasugrel (if applicable) or none of these treatments, where aspirin is considered a covariate.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-cohort study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AC) Platelet aggregation inhibitors excl. heparin

Platelet aggregation inhibitors excl. heparin

Medical condition to be studied

Myocardial infarction

Acute coronary syndrome

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

3.750

Study design details

Outcomes

The recurrent myocardial infarction (rMI) or cardiac death, Stroke, major (requiring hospitalization) and non-major bleeding, and death

---

Data analysis plan

Analyses will follow that of a matched case control study where cases are identified prospectively in a cohort and matched at each time point of occurrence to available controls in the cohort (without the events of interest), for age, sex and type of ACS at entry in the cohort (angina or MI). Odds ratios will be calculated using conditional logistic regression. All risk factors will be documented for cases and referents, which will be compared regarding the use of ticagrelor vs. clopidogrel or vs. prasugrel (in PCI if its use is sufficient). An adjusted odds ratio will be estimated in each case. Secondary analysis, using the cohort of reference will historically estimate the incidence of rMI, stroke and bleeding from the time of the occurrence of 'index' acute coronary syndrome up to 12 months after the ACS. The incidence rates of recurrent MI, stroke, death and bleeding will be produced, with their confidence intervals, by antiplatelet therapy.

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.

Composition of steering group and observers

AReMIS_CS_Contact list_30092013.pdf (109.15 KB)

Data sources

Data sources (types)

Other

Data sources (types), other

Case-control surveillance database

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