Secondary Prevention of Acute Coronary Events with Antiplatelet Agents: A cohort study in the SNIIRAM database (SPACE-AA)

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Last updated: 23/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS5987

Study ID

49886

DARWIN EU® study

No

Study countries

☐ France

Study description

The research question is to evaluate in real-life the use and the impact of ticagrelor and other antiplatelet agent (APA) in the secondary prevention of acute coronary syndrome (ACS). The main objective of effectiveness is to estimate the one-year incidence of the primary effectiveness endpoint (all-cause death, or hospitalisation for ACS, or hospitalisation for ischemic or undefined stroke) during ticagrelor exposure and during other APA exposure for secondary prevention of ACS. The main objective of safety is to estimate the one-year incidence of the primary safety endpoint (hospitalisation for major bleeding) during ticagrelor exposure and during other APA exposure for secondary prevention of ACS. The study is a cohort study in a national healthcare claims and hospitalisations database, of patients hospitalized in 2013 for an ACS with one-year previous history and at least one year follow-up in the database. APA exposure will be defined by claims for drug dispensation after discharge. For each APA, exposure will be defined by the first APA dispensation in the month after discharge, and the time between index ACS and last dispensation + 37 days (30 days of treatment + one week). The follow-up period after index ACS is at least one and up to two years, until 31 December 2014. The study period is defined by the years 2012 to 2014. The study population will be all patients hospitalised between 1 January and 31 December 2013 for an ACS, regardless of the type of treatment. According to the protocol, about 150 000 patients are hospitalised yearly at least once with a main diagnosis of unstable angina or myocardial infarction (MI). Taking into account the PLATO results, around 15 000 (10%) of death, MI or non-fatal stroke are expected after one year of follow-up.

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

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Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicholas Moore

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/11/2013

Study start date
Actual: 10/02/2015

Date of final study report
Actual: 20/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Aztrazeneca

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 topic:

Disease /health condition

Human medicinal product

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:

Main objective of effectiveness: Estimate the 1-year incidence of the primary effectiveness endpoint (all-cause death, hospitalisation for ACS, or for ischemic or undefined stroke) during ticagrelor exposure and during other APA exposure for secondary prevention of ACS.Main objective of safety: Estimate the 1-year incidence of the primary safety endpoint (hospitalisation for major bleeding).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AC) Platelet aggregation inhibitors excl. heparin

Platelet aggregation inhibitors excl. heparin

(N02BA01) acetylsalicylic acid

acetylsalicylic acid

Medical condition to be studied

Acute coronary syndrome

Population studied

Short description of the study population

Subject with acute coronary syndrome treated with ticagrelor and other antiplatelet agents obtained from the national healthcare claims and hospitalisations database for the study period of 2012 to 2014.

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

Patients with acute coronary syndrome

Estimated number of subjects

150000

Study design details

Outcomes

The primary effectiveness endpoint is a composite of all-cause death, hospitalisation for ACS, and hospitalisation for an ischemic or undefined stroke.The primary safety endpoint includes following events: hospitalisation for bleeding events (including haemorrhagic stroke). The secondary effectiveness endpoint is a composite of all-cause death, hospitalisation for ACS, hospitalisation for percutaneous coronary intervention or coronary artery by-pass grafting, and hospitalisation for an ischemic or undefined stroke.

Data analysis plan

Statistical analysis will be carried out according to a documented and approved Statistical Analysis Plan (SAP). The SAP describes statistical analysis as foreseen at the time of planning study. Statistical analysis will be performed after database lock using SAS® software (SAS Institute, last version, North Carolina, USA). Blind double programming will be used for the main outcome measures.Primary and secondary endpoints will be analysed using survival methods: The Kaplan Meier estimate for incidence of events and the Cox proportional hazard risk model to compare incidence between APA, with gender, age, initial SCA management and high-dimensional propensity score (hdPS) adjustment and matching.

Documents

Study publications

Blin P, Dureau-Pournin C, Benichou J, Bonello L, Dallongeville J, Danchin N, Fa…

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 source(s), other

National healthcare insurance and hospital-discharge summary database

France

Data sources (types)

Administrative healthcare records (e.g., claims)

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