Health Outcomes, Resource Use, costs in patients with Stable coronary artery disease a cohort study in the EGB database (HORUS)

First published: 12/02/2014

Last updated: 23/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5816

Study ID

49883

DARWIN EU® study

No

Study countries

France

Study description

The research question is to assess the burden of disease (healthcare resource utilization and cost, atherothrombotic events, major bleeding events, and mortality) in a French real world setting among 3 populations: i) Stable CAD population (patients with a history of MI at least one year ago), ii) High risk stable CAD population (stable CAD patients with additional risk factors), iii) PEGASUS-like population (high risk stable CAD patients with other main PEGASUS inclusion and exclusion criteria). The index date is defined by the date corresponding to one calendar year (365 days) following the patient's trigger event (i.e. from 1 January 2006 to 31 December 2011). The trigger event is defined by the date of a hospital record indicating myocardial infarctions (MI) or acute coronary syndrome (ACS) between 1 January 2005 and 31 December 2010. The follow-up period after index date is at least one and up to three years, until 31 December 2012 (ie three years for patients with an index date before 31 December 2009 and one year for patients with 31 December 2011 for index date). The study period is defined by the years 2005 to 2012. The study population will be all adult patients (≥18 years at the time of the trigger event) with a trigger event between 1 January 2005 and 31 December 2010. According to the protocol, about 5 600 patients with an ACS or MI have been identified in the EGB between 1 January 2005 and 31 December 2010.

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: 28/10/2013

Study start date

Actual: 20/11/2013

Date of final study report

Actual: 05/10/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Aztrazeneca

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

Disease epidemiology

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Main study objective:

To assess event rates and cumulative incidence rates of nonfatal MI, nonfatal stroke, major bleeding, and mortality during follow-up, and by specific time periods (follow-up periods 0-1 year, 1-2 years, 2-3 years).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10) DRUGS USED IN DIABETES

DRUGS USED IN DIABETES

(B01AC) Platelet aggregation inhibitors excl. heparin

Platelet aggregation inhibitors excl. heparin

(C07) BETA BLOCKING AGENTS

BETA BLOCKING AGENTS

(C09A) ACE INHIBITORS, PLAIN

ACE INHIBITORS, PLAIN

(C09B) ACE INHIBITORS, COMBINATIONS

ACE INHIBITORS, COMBINATIONS

(C09C) ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN

ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN

(C09D) ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), COMBINATIONS

ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), COMBINATIONS

(C10) LIPID MODIFYING AGENTS

LIPID MODIFYING AGENTS

(N02BA01) acetylsalicylic acid

acetylsalicylic acid

Medical condition to be studied

Coronary artery disease

Population studied

Short description of the study population

Subject with stable coronary artery disease (CAD) (patients with a history of MI at least one year ago), high risk stable CAD (stable CAD patients with additional risk factors), and PEGASUS-like patients (high risk stable CAD patients with other main PEGASUS inclusion and exclusion criteria) identified from French real world setting for the study period of 2005 to 2012.

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

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

5600

Study design details

Outcomes

Clinical events during follow-up as well as specific follow-up time periods (0-1 year, 1-2 years, 2-3 years): i) A composite of hospitalisation for non-fatal ACS (primary diagnosis ICD-10 codes I20.0-I21) or non-fatal stroke (ICD-10 codes I63-I64), and all-cause mortality, ii) Each event separately, iii) Hospitalisation for fatal and non-fatal major bleeding (ICD10 codes for bleeding). To describe baseline demographic and clinical characteristics at the time of trigger event and during the year between trigger event and index date.To describe treatment pattern during follow-up, as well as specific time periods (follow-up periods 0-1 year, 1-2 years, 2-3 years).To describe health care resource use and costs during follow-up as well as specific follow-up time periods.

Data analysis plan

Statistical analysis will be carried out by the Bordeaux pharmacoepi 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.Qualitative variables (dichotomous or categorical) will be described in terms of number and frequency. Quantitative variables will be described in terms of mean, standard deviation, median, first and third quartiles, as well as deciles.The Kaplan Meier estimate will be used to estimate the incidence of clinical events. The Cox proportional hazards risk model will be used to assess predictors of the composite clinical events.

Documents

Study publications

Blin P, Dureau-Pournin C, Lassalle R, Jové J, Thomas-Delecourt F, Droz-Perrotea…

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), other

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