Assessment of The High risk and unmEt Need in patients with Coronary Artery Disease and type 2 diabetes in France (ATHENA-F)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46548

EU PAS number

EUPAS27402

Study ID

46548

DARWIN EU® study

No

Study countries

☐ France

Study description

AstraZeneca is working on an indication extension of ticagrelor for the prevention of cardiovascular (CV) death, myocardial infarction (MI) or stroke in patients with coronary arterial disease (CAD), but without medical history of previous MI or stroke at high risk of atherothrombotic events due to type II diabetes mellitus (T2DM). The ATHENA-F study purpose is to assess the prevalence and burden of CAD-T2DM without prior MI or stroke in France, as well as of the population with inclusion and exclusion criteria of the THEMIS randomized controlled trial (THEMIS-like population), using the French nationwide claims database (SNDS). The first study population will include all T2DM patients identified in 2013-2014 with CAD but without MI or stroke history, and affiliated to the general scheme from 2008 to 2016 (data extraction period). Each patient will be followed 2 years or until death and will have 5-year history in the database. THEMIS-like population will include patients of this first population aged ≥50 years at index, without history of intracranial bleeding, renal failure requiring dialysis, cirrhosis of liver or liver cancer, gastro-intestinal bleeding (within 6 months), antiplatelet agent or anticoagulant treatment within 2 months around index date. For prevalent patients (both T2DM and CAD), index date will be 01/01/2013, for incident patients the first date of the second diagnosis between T2DM or CAD. The number of CAD-T2DM patients is estimated to 550,000 patients in the SNDS, and the prevalence of the two study populations will be assessed on 01/01/2013 and 31/12/2014. The CV events (stroke, MI, CV death, all-cause death, heart failure, bleeding, and composite CV events of MI, stroke, CV death) during the study period will be described in terms of crude incidence rate (Normal approximation), cumulative incidence rate (Kaplan-Meier estimator or Cumulative Incidence Function), and risk factors of the composite CV events (Cox proportional hazards model).

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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Primary lead investigator

Patrick Blin

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 12/07/2018

Study start date
Planned: 31/12/2018

Actual: 19/06/2019

Data analysis start date
Planned: 01/03/2019

Actual: 19/06/2019

Date of final study report
Planned: 28/02/2020

Actual: 20/03/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

ATHENA-F Protocol-v2.0-20180725.pdf(1.88 MB)

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

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:

The main objective is to estimate the prevalence of CAD-T2DM without prior MI or stroke in France, as well as of the population with inclusion and exclusion criteria of the THEMIS randomized controlled trial (THEMIS-like population).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Type 2 diabetes mellitus

Coronary artery disease

Population studied

Short description of the study population

All T2DM and CAD patients without MI or stroke history, identified and followed in the SNDS nationwide claims database.

Three populations were defined:
- CAD-T2DM population: all patients with T2DM diagnosis on 01/01/2014 plus CAD history and affiliated to the main healthcare insurance scheme (CNAMTS), because of incomplete history for other schemes included after 2011;
- CAD-T2DM population without prior MI-stroke: patients of the CAD-T2DM population without diagnosis of MI or stroke during the history period;

- THEMIS-like population: patients of the CAD-T2DM population without prior MI-stroke fulfilling the following criteria:

• Aged ≥ 50 years at index date;

• Without intracranial bleeding before index date;

• Without gastro-intestinal (GI) bleeding within 6 months before index date;

• Without renal failure requiring dialysis;

• Without cirrhosis of liver or liver cancer before index date;

• Without antiplatelet agent (APA) or anticoagulant treatments within 2 months before and after index date.

Exclusion criteria:

All subjects from all populations with the following criteria were excluded:

- Patients < 18 years at index date;

- Patients dead at index date;

- Patients not affiliated to the general scheme (Régime Général) between 2008 and 2016;

- Patients with less than 5 years of history period or incomplete follow-up (without death).

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

Type 2 diabetes mellitus, Coronary artery disease patients

Estimated number of subjects

550000

Study design details

Outcomes

MI, ischemic or unknown stroke, CV death, composite CV events (MI, stroke, CV death), all-cause death, heart failure, major organ specific bleeding as intracranial haemorrhage, other critical organ or site bleeding (intraspinal, intraocular, retroperitoneal, intraarticular or pericardial, or intramuscular), other bleeding (GI, urogenital and other bleeding) with transfusion, fatal bleeding.

Data analysis plan

Following analyses will be performed for CAD-T2DM without MI or stroke population and THEMIS-like population:- Description of patients (Flow-Chart, demographic, clinical and therapeutic characteristics at inclusion and during the follow-up)- Description of healthcare resources use and costs during the 2-year follow-up period according to the collective and national health insurance perspectives- Prevalence estimate of each population on 01/01/2013 and 31/12/2014 among French population, overall and according to age and gender- Cumulative incidence estimate of outcomes (stroke, MI, CV death, all-cause death, heart failure, bleeding, composite CV events of MI, stroke, CV death) using Kaplan-Meier estimator and Cumulative Incidence Function to take into account death as a competing risk, overall and according to 3 age-classes (<65, 65-75, >75)- Predictors estimate of the composite CV events using a multivariable Cox proportional hazards regression model with a stepwise method

Documents

Study results

ATHENA-F_Final study report_v1.0-20200320-print.pdf(7.96 MB)

Study publications

Blin P, Darmon P, Henry P, Guiard E, Bernard MA, Dureau-Pournin C, Maizi H, Tho…

Data management

Data sources

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