Cardiovascular-Renal-Metabolism comorbidity epidemiology and healthcare utilisation – Observational studies across Europe – French part of the study program (CaReMe Europe)

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46554

EU PAS number

EUPAS37569

Study ID

46554

DARWIN EU® study

No

Study countries

☐ France

Study description

Commonalities between cardiovascular, renal and metabolic (CaReMe) diseases with clinical overlap between these diseases and their associated complications are increasingly recognized. AstraZeneca conducts a European study program in 10 countries according to a common protocol to address specific unanswered questions on the epidemiology of CaReMe disorders and the impact of these on healthcare utilization, using the French claims database (SNDS) for the French part of the program. The French cohort will include all adult type 2 diabetes (T2D) patients in 2014 with a follow-up of 5 years and having 4-year history period before the index date (01/01/2014) in the database. The cardiovascular and renal disease-free T2D population will include all T2D patients without angina, unstable angina, atrial fibrillation, myocardial infarction (MI), heart failure (HF), coronary revascularisation, stroke, transient ischemic attack, peripheral artery disease (PAD), peripheral artery revascularisation, chronic kidney disease (CKD) or dispensing of nitrates within the 4-year period before the index date. Several co-morbid T2D populations will be defined as cardiorenal syndrome (HF and CKD) population, HF population, CKD population, stroke population, MI population and PAD population. It is expected for the study approximately 3 million of T2D population in 2015. The events of interest (cardiorenal disease HF or CKD, HF, CKD, PAD, MI, stroke, and all-cause death) during the study period will be described in terms of crude incidence rate (person-year), cumulative incidence/probability (in %, Kaplan-Meier estimator or Cumulative Incidence Function), and risk comparison for each event between disease-free and co-morbid populations (Cox proportional hazards model or Fine and Grey Model). Specific cost (all payer perspective) of HF, CKD, cardiorenal diseases (HF or CKD), PAD, MI, or stroke will be estimated during the follow-up in T2D patients free from cardiovascular and renal diseases.

Study status

Ongoing

Research institutions and networks

Institutions

University of Bordeaux

France

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Institution | Educational Institution

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: 26/09/2019

Study start date
Planned: 31/10/2020

Actual: 01/12/2020

Date of final study report
Planned: 31/03/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Other

If ‘other’, further details on the scope of the study

Healthcare resource cost study

Main study objective:

The main objective is to estimate the incidence rate of the first specific cardiorenal event (HF, CKD, cardiorenal diseases HF or CKD, PAD, MI, or stroke) in T2D patients free from cardiovascular and renal diseases.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Type 2 diabetes mellitus

Cardiac failure

Chronic kidney disease

Myocardial infarction

Cerebrovascular accident

Peripheral arterial occlusive disease

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

3346431

Study design details

Outcomes

Outcomes and comorbidities (main analysis): main, linked, or associated diagnoses of hospitalisation associated with cardiorenal diseases (HF or CKD), HF, CKD, PAD, MI, stroke, and all-cause death. Outcomes (sensitivity analysis): main diagnosis of hospitalisation associated with cardiorenal diseases (HF or CKD), HF, CKD, PAD, MI, stroke, and all-cause death.

Data analysis plan

-Incidence estimate of HF, CKD, cardiorenal diseases (HF or CKD), PAD, MI, stroke, (first event) in cardiovascular and renal disease-free T2D population, using incidence rate and Cumulative Incidence Function (CIF), to take death into account as a competing risk -Incidence estimate of PAD, MI, stroke, or all-cause death in comorbid T2D population, using incidence rate and Kaplan-Meier estimator (for all-cause death) or CIF (for other outcomes) -Incidence

comparison of each outcome between disease-free and comorbid populations performed using a multivariable Cox proportional hazards regression model (disease-free patients as the reference category). Sensitivity analyses performed using multivariable Fine and Gray regression models for all outcomes except death -Description of healthcare resources use and cost (all payer perspective) of HF, CKD, cardiorenal diseases (HF or CKD), PAD, MI, or stroke (first event) for 5 years in T2D patients free from cardiovascular and renal diseases.

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