Patient characteristics and cardiovascular and mortality outcomes in patients with type 2 diabetes mellitus initiating treatment with sodium-glucose co-transporter-2 inhibitors and other antidiabetic medications in Finland

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Study | Planned

Administrative details

EU PAS number

EUPAS21945

Study ID

39983

DARWIN EU® study

No

Study countries

Finland

Study description

This observational study will describe patient characteristics and rate of cardiovascular (CV) and mortality outcomes in patients with type 2 diabetes mellitus (T2DM) who are initiating use or treatment with sodium-glucose co-transporter-2 (SGLT-2) inhibitors and other diabetes medications (other glucose lowering drugs). The study will analyze the risk of hospitalization for heart failure (HF), other CV outcomes, severe hypoglycemia, kidney disease (KD), and all-cause mortality in T2DM patients who initiate use or treatment with SGLT-2s compared to patients initiating other glucose lowering drugs (GLD) in Finland.

Study status

Planned

Research institutions and networks

Institutions

EPID Research Oy

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Institution

Contact details

Study institution contact

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Study contact

Fabian.Hoti@iqvia.com

Primary lead investigator

Fabian Hoti

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 18/10/2017

Study start date

Planned: 31/01/2018

Date of final study report

Planned: 31/12/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca Nordic Baltic

Study protocol

CVD REAL FINLAND Non Interventional Study Protocol v1.0 FINAL-v4_signed.pdf (607.96 KB)

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:

Effectiveness study (incl. comparative)

Main study objective:

The primary objective of this study is to compare the risk for hospitalization for heart failure, in patients with T2DM who are new users of SGLT-2s as a class or dapagliflozin separately, versus an active comparison group including patients with T2DM who are new users of other GLD.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

DAPAGLIFLOZIN

Anatomical Therapeutic Chemical (ATC) code

(A10BK) Sodium-glucose co-transporter 2 (SGLT2) inhibitors

Sodium-glucose co-transporter 2 (SGLT2) inhibitors

Medical condition to be studied

Type 2 diabetes mellitus

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

400000

Study design details

Outcomes

Hospitalization for heart failure, Other CV outcomes, severe hypoglycemia, KD, all-cause mortality and health care resource utilization

Data analysis plan

The event rates and baseline characteristics for each treatment group will be summarized descriptively. Propensity scores (PS) will be calculated to assess comparability between SGLT-2 users, dapagliflozin users, and the groups of matched comparators (DPP-4 and other GLD users). The primary objective is to provide a formal statistical comparison between the treatment and comparator group with respect to hospitalizations for HF using a hazard ratio (HR) (or other appropriate measure).

Data management

ENCePP Seal

Signed checklist for study protocols

ER-9565_ENCePPChecklistforStudyProtocols_Protocol version 1_20180504_signed.pdf(1.54 MB)

Data sources

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Causes of Death Registry, National Prescription Register including drug purchases and reimbursement decisions, National Hospital Care Register, National Primary Care Register, National register for institutionalizations (other than hospitalizations)

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