Non-interventional study on the effectiveness and safety of Empagliflozin compared with DPP-4 inhibitors in patients with type 2 diabetes in the United States

First published: 13/09/2017

Last updated: 02/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS20677

Study ID

21657

DARWIN EU® study

No

Study countries

☐ United States

Study description

The main objective of the proposed study is to compare selected CV effectiveness outcomes in patients with T2DM initiating empagliflozin compared to propensity score (PS) matched patients with T2DM initiating a DPP-4 inhibitor in sequential analyses within periodically updated cohorts in the U.S., secondary objectives include other effectiveness outcomes, safety outcomes, and healthcare utilization outcomes.

Study status

Ongoing

Research institutions and networks

Institutions

Brigham and Women's Hospital

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Elisabetta Patorno

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/12/2016

Study start date
Planned: 15/10/2017

Actual: 15/10/2017

Data analysis start date
Planned: 15/10/2017

Actual: 15/10/2017

Date of final study report
Planned: 31/03/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

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)

Safety study (incl. comparative)

Main study objective:

To compare selected CV effectiveness outcomes in patients with T2DM initiating empagliflozin compared to propensity score (PS) matched patients with T2DM initiating a DPP-4 inhibitor in sequential analyses within periodically updated cohorts in the U.S. secondary objectives include other effectiveness outcomes, safety outcomes, and healthcare utilization outcomes.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Sequential matched cohort study

Study drug and medical condition

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

EMPAGLIFLOZIN

SITAGLIPTIN

SAXAGLIPTIN

LINAGLIPTIN

ALOGLIPTIN

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

232000

Study design details

Outcomes

- 3-point MACE hospital admission for MI, hospital admission for stroke, CV mortality and its individual components- hospital admission for HF- all-cause mortality, - Coronary revascularization procedure - End-stage renal disease - Initiation of laser treatment for retinopathy- Bone fracture- Diabetic ketoacidosis- Severe hypoglycemia- All urinary tract cancers and its individual components, additional cancers may be considered.- Lower-limb amputation- Acute kidney injury requiring dialysis- Healthcare resource utilization- Cost

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Data analysis plan

We will receive new data as they become available on a periodic basis (every 12 months) and, at each data cut, we will update the original set of data, form sequential cohorts by propensity score (PS) matching within 12-month blocks of time, follow patients for each of the outcomes of interest in a prospective manner, and estimate measures of effect using person-time based analyses among patients who initiate empagliflozin versus DPP-4 inhibitor use. Unadjusted and adjusted relative risks (hazard ratios) and rate differences will be estimated. In adjusted analyses, we will use propensity score (PS) matching to balance potential confounders.

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 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