Clinical and economic impact of 2nd line initiation of empagliflozin after metformin, as compared to 2nd line initiation of sulfonylurea after metformin in patients with type 2 diabetes and cardiovascular disease

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47812

EU PAS number

EUPAS43815

Study ID

47812

DARWIN EU® study

No

Study countries

☐ United States

Study description

Status - finalized This study has been cancelled due to feasibility – did not attain sample size.

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Effie Kuti

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2021

Actual: 02/07/2021

Study start date
Planned: 30/10/2021

Actual: 01/11/2021

Date of final study report
Planned: 15/07/2022

Actual: 17/06/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

Empagliflozin vs Sulfonylureas (Protocol) V3 (002).pdf(622.15 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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

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

Burden

Data collection methods:

Secondary use of data

Main study objective:

Evaluate clinical outcomes (specifically cardiovascular outcomes like hospitalization for heart failure), and healthcare cost, and resource utilization, among patients on empagliflozin as an add-on therapy to metformin versus patients on sulfonylureas as an add-on therapy to metformin in patients with T2D and CVD.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

JARDIANCE

Medical condition to be studied

Diabetes mellitus

Population studied

Short description of the study population

Type 2 Diabetes (T2D) patients with Cardiovascular Disease (CVD).

Inclusion criteria:

• Prevalent metformin use + initiation of empagliflozin OR prevalent metformin use + initiation of a sulfonylurea

• ≥18 years of age at index date during study observation

• ≥1 inpatient and/or ≥ 2 outpatient claims denoting T2D diagnosis (in any position) in the 12 months prior to index date

• ≥1 inpatient and/or ≥2 outpatient claims denoting CVD (in any position) diagnosis in the 12 months prior to index date

• ≥2 months post-index date

• ≥12 months of no exposure to T2D medications in the pre-index period (excluding metformin in both arms)

• ≥12 months of continuous enrollment prior to index date

Exclusion criteria:

• Diagnosis of Type 1 Diabetes, secondary, or gestational diabetes in the 12 months prior to index date

• Diagnosis of severe comorbidities including malignancy, end-stage renal disease, human immunodeficiency virus, Hepatitis C infection, or organ

transplant in the 12 months prior to index date

• Admission to nursing home in the 12 months prior to index date

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 patients

Estimated number of subjects

265

Study design details

Outcomes

First hospitalization for heart failure (HHF) (we will first analyze this by looking at diagnosis code in any position, we will then run the analysis considering diagnosis coding in either the principal or secondary position). Healthcare utilization outcomes: hospitalizations, emergency department (ED) visits, length of stay, number of filled drugs, outpatient visits All cause cost outcomes: Total cost of care, divided by medical (inpatient costs, outpatient costs, emergency costs) and pharmacy costs (all reported in Per Patient Per Month (PPPM) costs)

Data analysis plan

This study will be a non-interventional study using existing data from January 1, 2014 to the date of the latest available data from IQVIA (detailed below). Data available after March 31, 2020 will not be used due to the potential confounding events of coronavirus. The study will analyze the clinical and economic effect of empagliflozin in T2D patients with CVD. Empagliflozin initiators as an add-on therapy to metformin, comprise the treatment population. Patients initiating sulfonylureas as add-on to metformin comprise the control population.

Data management

Data sources

Data source(s), other

IMS LifeLink: PharMetrics Plus - US

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