Post-authorization safety study in patients with type 2 diabetes mellitus to assess the incidence of ketoacidosis, severe complications of urinary tract infection, volume depletion, and dehydration among patients treated with EMPAGLIFLOZIN or DPP-4 inhibitors in Saudi Arabia (Post-authorization safety study in type 2 diabetic)

First published: 25/07/2017

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Study Ongoing

Administrative details

EU PAS number

EUPAS20025

Study ID

27527

DARWIN EU® study

No

Study countries

☐ Saudi Arabia

Study description

This will be non-interventional study with new data collection. The study will use a “new users” design and compare new users of EMPAGLIFLOZIN to new users of DPP-4 inhibitors. The index date will be defined as the date on which each identified new user receives the index prescription for EMPAGLIFLOZIN or a DPP-4 inhibitor.Number of recruited patients will be comparable in each group within a given timeframe (i.e. each site will ensure to recruit similar number per month for each group). Propensity scores based on information prior to the index date will be used to account for potential confounding.Patients will be follow-up for 12 months after index date.

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ahmed Mansour

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 22/12/2016

Actual: 26/12/2016

Study start date
Planned: 30/09/2018

Actual: 27/09/2018

Data analysis start date
Planned: 30/06/2020

Date of final study report
Planned: 31/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

1245.149 @ 20170723 - Clinical Trial Protocol Ver-2.0 _updated on TC 23-May-2017_clean version_PR2.pdf(722.02 KB)

BI PASS_Study protocol NIS_Version 3_dated 03May2018.pdf(474.85 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Other study registration identification numbers and links

SFDA application no. 17062102 on SCTR

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Post-authorization safety study in patients with type 2 diabetes mellitus to assess the incidence of ketoacidosis, severe complications of urinary tract infection, volume depletion, and dehydration among patients treated with EMPAGLIFLOZIN or DPP-4 inhibitors in Saudi Arabia

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

JARDIANCE

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)

Estimated number of subjects

1500

Study design details

Outcomes

To estimate the incidence of:- Ketoacidosis- Severe urinary tract infections- Volume depletion- Dehydrationin type 2 diabetes mellitus (T2DM) patients initiating EMPAGLIFLOZIN compared with the incidence in T2DM patients initiating Dipeptidyl peptidase-4 (DPP-4) inhibitors, To estimate the risk of each primary outcome with respect to the following definition of exposure:the Ramadan period

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Data analysis plan

For the incident users of EMPAGLIFLOZIN and of DPP4i, analysis will be performed using the “as-treated” (AT) approach. This corresponds to censoring individuals who discontinue use of the index drug, i.e. either switch from the index drug to any other of the index drug (EMPAGLIFLOZIN or DPP-4 inhibitor) during follow-up or stop using the index drugFor the assessment of the primary and secondary objectives, the main data analysis will be conducted in two stages: - Construction of the propensity score (PS) by modelling the exposure to EMPAGLIFLOZIN vs. DPP-4 inhibitor - Estimation of the effect of exposure to EMPAGLIFLOZIN on the ketoacidosis, severe urinary tract infections, volume depletion and dehydration compared to those exposed to DPP-4 inhibitor.

Data management

Data sources

Data sources (types)

Drug dispensing/prescription data

Spontaneous reports of suspected adverse drug reactions

Other

Data sources (types), other

Prospective patient-based data collection

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