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

Last updated: 16/10/2026

Study Finalised

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

Finalised

Contact details

Study institution contact

Ahmed Mansour ahmed.mansour@boehringer-ingelheim.com

Study contact

ahmed.mansour@boehringer-ingelheim.com

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

Actual: 14/09/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

1245-0149_Prot_redacted.pdf (14.87 MB)

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

1245-0149; NCT03764631

SFDA application no. 17062102 on SCTR

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

"new users" design

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

Medicinal product name

JARDIANCE

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

EMPAGLIFLOZIN

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

Patients diagnosed with T2DM in Saudi Arabia

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Estimated number of subjects

1.500

Study design details

Setting

The sites were primary care clinics, hospital clinics and other outpatient clinics. 25 sites in Saudi Arabia. The treating physicians will mainly be general practitioners (GPs) and/or specialists including endocrinologist, diabetologist & internists.

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

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.

Documents

Study results

1245-0149_Synopsis.pdf (364.89 KB)

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)

Patient surveys

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