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Post-authorization safety study to assess the risk of diabetic ketoacidosis among type 2 diabetes mellitus patients treated with ertugliflozin compared to patients treated with other antihyperglycemic agents (MK-8835-062)

First published:
17/10/2019
Last updated 30/10/2024
Study
Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50276

EU PAS number

EUPAS31718

Study ID

50276

DARWIN EU® study

No

Study countries

United States

Study description

A non-interventional cohort study will be conducted using the Reagan-Udall Foundation for the Food and Drug Administration (FDA)’s Innovation in Medical Evidence and Development Surveillance Distributed Database (IMEDS-DD), a subset of the FDA Sentinel Distributed Database. This study will address the research question of whether new use of ertugliflozin is associated with an increased risk of diabetic ketoacidosis (DKA), compared to new use of other

non-sodium–glucose cotransporter 2 (SGLT2) inhibitor antihyperglycemic agents (AHAs) among type 2 diabetes mellitus (T2DM) patients. Propensity score matching will be used for confounding adjustment, followed by Cox proportional hazards models for risk estimation.

Study status

Finalised

Research institution and networks

Institutions

Reagan-Udall Foundation
First published:
01/02/2024
Last updated 01/02/2024
Institution

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Study contact
ClinicalTrialsDisclosure@merck.com
Primary lead investigator

Sengwee Toh

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual:
03/07/2018

Study start date

Planned:
24/10/2019
Actual:
17/10/2019

Data analysis start date

Planned:
31/03/2024

Date of interim report, if expected

Planned:
31/12/2021
Actual:
09/12/2021

Date of final study report

Planned:
31/10/2024
Actual:
11/10/2024

Sources of funding

Other
Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC, Pfizer Inc.

Study protocol

MK-8835-062-01-v1-Protocol_final redaction.pdf(891.27 KB)
MK-8835-062-00-v4-Protocol_Final Redaction.pdf(3.92 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:
Herbal medicinal product
Study type:
Non-interventional study
Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness
Safety study (incl. comparative)
Main study objective:

1. To assess the risk of DKA among new users of ertugliflozin relative to new users of sulfonylureas (SUs) or thiazolidinediones (TZDs).
2. To assess the risk of DKA among new users of ertugliflozin relative to new users of incretin-based drugs i.e. dipeptidyl peptidase 4 (DPP-4) inhibitors or glucagon-like peptide-1 (GLP-1) receptor agonists.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

Segluromet
Steglatro
Steglujan

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

ERTUGLIFLOZIN

Anatomical Therapeutic Chemical (ATC) code

(A10BK04) ertugliflozin

Medical condition to be studied

Diabetic ketoacidosis

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

8819

Study design details

Outcomes

Hospitalization for DKA identified from principal discharge diagnosis of inpatient claims.

Data analysis plan

Baseline demographic and clinical characteristics will be described by exposure group before and after propensity score matching. Incidence rates (and 95% confidence interval) of DKA will be calculated by exposure group. The differences between the exposure groups in terms of time to DKA will be assessed using Kaplan-Meier survival curves with log rank test. Cox proportional hazards models will be used separately to compare the risk of DKA among new users of ertugliflozin to that among new users of SU/TZD, and to compare the risk of DKA among new users of ertugliflozin to that among new users of incretin-based drugs. Subgroup analysis will be further conducted by concomitant insulin use on the index date. Sensitivity analyses pre-defined in the protocol will be conducted to assess the robustness of the study results.

Documents

Study report
MK-8835-06-interim-report-dec-2021_final redaction.pdf(1.83 MB)
MK-8835-062-02-interim-report-dec-2022_final redaction.pdf(1.86 MB)
MK-8835-062-second-interim-report-nov-2022_final redaction.pdf(1.07 MB)
p62mk8835-final-study-report-AUG-2024_final-redaction.pdf(1.25 MB)
Study, other information
MK-8835-062-02-interim-report-dec-2022_final redaction.pdf(1.86 MB)
MK-8835-062-second-interim-report-nov-2022_final redaction.pdf(1.07 MB)

Data management

Data sources

Data sources (types)

Administrative data (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