SGLT2 Inhibitors and the Risk of Hospitalization for Fournier’s Gangrene: a Nested Case-control Study (MK-8835-067)

First published: 04/04/2019

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS28953

Study ID

30437

DARWIN EU® study

No

Study countries

☐ United States

Study description

The proposed study is a nested case-control study that will be conducted within a population-based cohort from the Truven Health MarketScan™ databases. The cohort will include patients 18 years of age or older who are prescribed at least one antihyperglycemic agent between April 1, 2013 (when the first sodium-glucose cotransporter 2 (SGLT2) inhibitor was available in the United States) and March 31, 2018 (latest available data). A nested case-control analysis will be carried out to provide the relative risks of Fournier's gangrene with SGLT2 inhibitors compared to other non-SGLT2 inhibitor antihyperglycemic agents (AHAs) in a real-world setting.

Study status

Finalised

Research institutions and networks

Institutions

Merck & Co.

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Institution

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme Corp.
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Study contact

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 10/10/2018

Study start date

Planned: 15/04/2019

Actual: 15/04/2019

Data analysis start date

Planned: 20/05/2019

Actual: 23/05/2019

Date of final study report

Planned: 28/06/2019

Actual: 27/06/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme, Corp.

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

VEAP ID NO: 8347EPIDEMIOLOGY NO.: EP02039.006

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The primary objective is to assess whether the use of sodium-glucose cotransporter 2 (SGLT2) inhibitors was associated with an increased risk of hospitalization for Fournier’s gangrene as compared with other non-SGLT2-inhibitor antihyperglycemic agents (AHAs).

Study Design

Non-interventional study design

Case-control

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10BK) Sodium-glucose co-transporter 2 (SGLT2) inhibitors

Sodium-glucose co-transporter 2 (SGLT2) inhibitors

Medical condition to be studied

Necrotising fasciitis

Population studied

Short description of the study population

The cohort will include patients ≥18 years who are prescribed at least one antihyperglycemic agent between April 1, 2013 (when the first SGLT2 inhibitor was available in the US) and March 31, 2018 (latest available data).

We will identify all patients who were prescribed at least one AHA agent between April 1, 2013 and March 31, 2018 and had at least 1 claim of type 2 diabetes diagnosis during the study period. Cohort entry date will be defined as the date of the first prescription claim for an AHA during the study period. The AHAs considered at cohort entry will consist of metformin, sulfonylureas (SU), thiazolidinediones (TZD), acarbose, meglitinides, a prandial glucose regulator, dipeptidyl peptidase-4 (DPP-4) inhibitors, glucagon-like peptide-1 (GLP1) receptor agonists, SGLT-2 inhibitors and insulin. We will restrict our cohort to patients aged at least 18 years of age at the time of their cohort entry and who are continuously enrolled in the health plan for ≥ 6 months before the study cohort entry. We will exclude patients who had previously received a diagnosis of human immunodeficiency virus (HIV) infection, or patients who had a previous diagnosis of Fournier’s gangrene before study cohort entry. Patients with a principal diagnosis of type 1 diabetes, women with a diagnosis of gestational diabetes and those with a principal diagnosis of polycystic ovary syndrome (for whom metformin can be prescribed) will also be excluded.

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

600

Study design details

Outcomes

The study's primary outcome will be hospitalization for Fournier’s gangrene.

Data analysis plan

Descriptive statistics will be used to summarize the characteristics of the cases and matched controls. A nested case-control analysis will then be performed to investigate the association between the use of SGLT2 inhibitors and the incidence of Fournier's gangrene hospitalization. Conditional logistic regression will be used to estimate odds ratios and corresponding 95% confidence intervals for the association between SGLT2 inhibitors and the risk of Fournier's gangrene, with the use of risk set sampling, these odds ratios are unbiased estimators of the hazard ratio.

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