RRA-21430: Acute Pancreatitis in Patients with Type 2 Diabetes Who are New Users of Canagliflozin as Compared with New Users of Other Antihyperglycemic Agents: A Retrospective Cohort Study Using Large Claims Databases in the United States

First published: 11/04/2018

Last updated: 30/03/2020

Study Finalised

Administrative details

EU PAS number

EUPAS23531

Study ID

34358

DARWIN EU® study

No

Study countries

United States

Study status

Finalised

Research institutions and networks

Institutions

Johnson & Johnson

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Zhong Yuan

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/03/2018

Actual: 20/03/2018

Study start date
Planned: 21/03/2018

Actual: 21/03/2018

Date of final study report
Planned: 11/09/2018

Actual: 04/09/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen Research & Development, LLC

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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

This observational, retrospective, new-user cohort study aims to 1. Estimate the incidence rate of acute pancreatitis in type 2 diabetes (T2D) patients newly exposed to canagliflozin and comparator antihyperglycemic agents (AHAs), and 2. Compare the hazard of acute pancreatitis in T2D patients newly exposed to canagliflozin vs. comparator AHAs, based on propensity-score matched cohorts.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Post Authorization Safety Study (PASS)

Study drug and medical condition

Name of medicine

INVOKANA

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

CANAGLIFLOZIN

Anatomical Therapeutic Chemical (ATC) code

(A10BK02) canagliflozin

canagliflozin

Medical condition to be studied

Pancreatitis acute

Population studied

Short description of the study population

Adult patients with T2DM who were newly exposed to a drug of interest (ie, canagliflozin or a comparator drug) between April 1, 2013 and September 30, 2017.

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

354000

Study design details

Outcomes

Acute pancreatitis

Data analysis plan

Descriptive statistics of incidence rate will be presented. Comparative analysis will be conducted using both ITT and PP approaches for new users of canagliflozin vs. new users of alternative AHA therapy. Conditional Cox proportional hazards model based on time-to-first event approach, using propensity-score matched sets (with variable matching), will be used to estimate the comparative treatment effect size. The propensity score will be estimated through large-scale regularized regression, with demographics, all prior conditions/drugs/procedures, risk scores, utilization density as baseline covariates. Hochberg step-up procedure will be applied and adjusted p-values will be reported in addition to empirical p-values to control for multiple comparisons. A set of negative control outcomes will also be used to calibrate empirically observed p-values. Patients with a history of any form of pancreatitis will be evaluated and included in the study, if balance at baseline is achieved.

Documents

Study results

CSR Synopsis_RRA-21430_EUPAS23531.pdf(130.73 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)

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