

# 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

## Study status

Finalised

## Research institutions and networks

### Institutions

#### Johnson & Johnson

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

Zhong Yuan RA-RNDUS-CInclTrlsEU@its.jnj.com

Study contact

[RA-RNDUS-CInclTrlsEU@its.jnj.com](mailto:RA-RNDUS-CInclTrlsEU@its.jnj.com)

### 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 type list

**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

**Medicinal product name**

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