# Incidence of Diabetic Ketoacidosis among Patients with Type 2 Diabetes Mellitus Treated with SGLT2 inhibitors or Other Antihyperglycemic Agents- A Retrospective, Observational, New-User Cohort Study Using 4 Administrative Claims Databases in the US

**First published:** 26/04/2018

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Study Finalised

## Administrative details

**EU PAS number**

EUPAS23705

**Study ID**

34362

**DARWIN EU® study**

No

**Study countries**

United States

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Johnson & Johnson

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

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**Institution**

# Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Lu Wang

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**
Planned: 18/04/2018

Actual: 18/04/2018

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**Study start date**
Planned: 18/04/2018

Actual: 18/04/2018

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**Date of final study report**
Planned: 08/10/2018

Actual: 01/10/2018

# 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

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

EU RMP category 3 (required)

# Methodological aspects

## Study type

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**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

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**Main study objective:**

The main objective of this study is to compare diabetic ketoacidosis (DKA) incidence between new users of sodium-glucose co-transporter 2 inhibitors (SGLT2i, combined and separate) and new users of other antihyperglycemic agents (AHAs) among patients diagnosed with type 2 diabetes (T2DM). This study will also identify precipitating events and evaluate risk factors for incident DKA.

# Study Design

**Non-interventional study design**

Cohort

# 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**

Diabetic ketoacidosis

## Population studied

**Short description of the study population**

Patients who had a diagnosis of T2DM preceding new use of an SGLT2i or at least one pre-specified comparator AHAs during the study period and had at least 365 days of continuous enrollment prior to the first day of new drug exposure (index date).

**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**

409.360

## Study design details

**Outcomes**

Diabetic ketoacidosis

**Data analysis plan**

The crude incidence rates of DKA in the different AHA new-user groups will be estimated as the number of incident DKA cases divided by the total follow-up time at risk. Baseline patient characteristics including risk factors for DKA will be summarized for those treated with SGLT2i versus other AHAs. A conditional Cox proportional hazards model based on time-to-first event approach will be used to estimate Hazard Ratio (HR) associated with SGLT2i (combined and separate) versus other AHAs, with each exposure propensity-score matched set treated as a separate stratum in Cox model. The exposure propensity score will be estimated through large-scale regularized regression, with demographics, all prior conditions/drugs/procedures, risk scores, utilization density as baseline covariates. An empirical p-value calibration using negative control outcomes will be conducted to address potential systematic bias. HRs, 95% CIs, pre- and post- calibration p values will all be reported.

## Documents

**Study results**

CSR Synopsis_RRA-21651_EUPAS23705.pdf (131.75 KB)

# Data management

## 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