

# 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 an Administrative Claims Database in the US

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS20065

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### Study ID

20195

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### DARWIN EU® study

No

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## Study countries

 United States

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## Study status

Finalised

## Research institutions and networks

### Institutions

[NA \(database study\)](#)

## Contact details

### Study institution contact

Yiting Wang [ywang28@its.jnj.com](mailto:ywang28@its.jnj.com)

**Study contact**

[ywang28@its.jnj.com](mailto:ywang28@its.jnj.com)

### Primary lead investigator

Yiting Wang

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 01/06/2015

Actual: 01/06/2015

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### **Study start date**

Planned: 25/06/2015

Actual: 25/06/2015

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### **Date of final study report**

Planned: 31/03/2017

Actual: 31/03/2017

## 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?**

No

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

**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  
Other

**If 'other', further details on the scope of the study**

Primary scope: Comparison of adverse event risk between user of index drugs and comparator drugs.

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To compare the incidence of diabetic ketoacidosis (DKA) among patients diagnosed with type 2 diabetes and pair-matched on exposure propensity scores (EPS) for new use of any SGLT2 inhibitor class versus new use of various other antihyperglycemic agents (AHAs), combined as one group.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

INVOKANA

VOKANAMET

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

CANAGLIFLOZIN

DAPAGLIFLOZIN

METFORMIN

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**Anatomical Therapeutic Chemical (ATC) code**

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

Sodium-glucose co-transporter 2 (SGLT2) inhibitors

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**Medical condition to be studied**

Diabetic ketoacidosis

## Population studied

**Short description of the study population**

Patients with Type 2 Diabetes Mellitus treated with SGLT2 inhibitors or other antihyperglycemic agents.

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**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)
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## Special population of interest

Other

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## Special population of interest, other

Diabetes mellitus patients

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## Estimated number of subjects

60392

# Study design details

## Outcomes

First incident diabetic ketoacidosis diagnosis recorded in hospital or emergency room over the study period.

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## Data analysis plan

Baseline characteristics are summarized for patients treated with SGLT2i versus other AHAs. Between-group differences are assessed using Wilcoxon rank-sum tests for continuous variables and chi-squared tests for categorical variables. The standardized difference after propensity-score matching are also presented. Large scale exposure propensity score is estimated using regularized logistic regression models. The crude incidence rates of DKA in each AHA new-user cohorts are estimated as the number of first incident DKA cases divided by the total at-risk follow-up time, reported as number of cases per 1,000 person-years at risk. We use a conditional Cox proportional hazards model to estimate hazard ratio associated with SGLT2i versus other AHAs. Each propensity-score matched set is treated as a separate stratum in Cox model. P-values  $<0.05$  is considered statistically significant, all stat. tests are two-sided. Empirical p-value calibration is conducted to address potential systemic bias

## 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

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

## **Data characterisation conducted**

Unknown