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

Study ID

20195

DARWIN EU® study

No

Study countries

United States

Study status

Finalised

Research institutions and networks

Institutions

NA (database study)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Yiting Wang

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2015

Actual: 01/06/2015

Study start date
Planned: 25/06/2015

Actual: 25/06/2015

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

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

Study type:

Non-interventional study

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

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

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

CANAGLIFLOZIN

DAPAGLIFLOZIN

METFORMIN

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

Diabetic ketoacidosis

Population studied

Short description of the study population

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

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

Diabetes mellitus patients

Estimated number of subjects

60.392

Study design details

Outcomes

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown