Incidence of Diabetic Ketoacidosis among Patients with Type 2 Diabetes in the United States

First published: 12/04/2016

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS13060

Study ID

26317

DARWIN EU® study

No

Study countries

- [ ] Sweden
- [ ] United States

Study description

This study will estimate the incidence of diabetic ketoacidosis among patients diagnosed with T2DM initiating prescribed diabetes medication overall and by diabetes medication class and combinations of classes. This will be retrospective cohort analysis conducted in United States-based administrative claims data.

Study status

Finalised

Research institutions and networks

Institutions

Truven Health Analytics

AstraZeneca, Sweden

Contact details

Study institution contact

Amanda Farr amanda.farr@truvenhealth.com

Study contact

amanda.farr@truvenhealth.com

Primary lead investigator

Jesús Medina

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/10/2015

Actual: 15/10/2015

Study start date
Planned: 01/01/2012

Actual: 01/01/2012

Data analysis start date
Planned: 01/08/2016

Date of final study report
Planned: 09/12/2016

Actual: 04/08/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

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

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to estimate the incidence of diabetic ketoacidosis among patients diagnosed with type 2 diabetes mellitus initiating prescribed diabetes medications overall and by diabetes medication class and combinations of classes.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10) DRUGS USED IN DIABETES

DRUGS USED IN DIABETES

Medical condition to be studied

Diabetic ketoacidosis

Population studied

Short description of the study population

Patients diagnosed with Type 2 Diabetes (T2DM) initiating prescribed diabetes medication overall and by diabetes medication class and combinations of classes

---

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

222000

Study design details

Outcomes

The primary outcome will be the presence and number of diabetic ketoacidosis events defined as an inpatient or emergency room claim with a diagnosis for diabetic ketoacidosis (ICD-9-CM 250.10, ICD-9-CM 250.12) in any diagnosis field while patient is treated with an antidiabetes medication. The secondary and exploratory outcomes are different versions of the definitions for diabetic ketoacidosis, using ICD-9-CM codes 249.10, 249.11, 276.2 and evaluating claims for all settings (inpatient admissions, emergency room visits, and outpatient visits).

Data analysis plan

The analyses for this study will be unadjusted analyses displaying DKA incidence rates for all patients and for each of the examined diabetes

medication classes/pre-specified combinations of classes. Incidence rates will be calculated as the number of patients with a DKA event divided by the sum of person-time of follow up. Incidence rates and 95% confidence intervals will be presented. Incidence rates will be standardized by age and sex. Incidence rates will also be presented for a subset of patients with no prior DKA diagnosis.

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