PCSCVM003617/ A Real-World Database Study of Canagliflozin Utilization in Type 1 Diabetes Patients Over Time among European Countries

First published: 14/06/2022

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47809

EU PAS number

EUPAS47585

Study ID

47809

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

Johnson & Johnson

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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: 08/06/2022

Actual: 08/06/2022

Study start date
Planned: 31/03/2023

Actual: 07/03/2023

Date of final study report
Planned: 30/06/2024

Actual: 04/06/2024

Sources of funding

- Other

More details on funding

Janssen R&D

Study protocol

21Oct2024-REDACTED_Protocol-FD-PCSCVM003617-EUPAS47585.pdf(2.6 MB)

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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

The primary objectives of this study are to describe the time-trend of canagliflozin utilization in patients with T1DM using real-world databases in European countries with high cumulative exposure, including the UK, Spain, Italy, and Belgium.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Qualitative study including document analysis and qualitative interviews

Study drug and medical condition

Name of medicine

INVOKANA

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

CANAGLIFLOZIN

METFORMIN

Anatomical Therapeutic Chemical (ATC) code

(A10BK02) canagliflozin

canagliflozin

Medical condition to be studied

Type 1 diabetes mellitus

Type 2 diabetes mellitus

Population studied

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)

Estimated number of subjects

14249

Study design details

Data analysis plan

Analysis will be conducted within each database. The utilization pattern of canagliflozin in patients with type 1 diabetes mellitus (T1DM) will be described, with continuous variables summarized using mean ±standard deviation, median, and interquartile range and categorical variables summarized using counts and proportions. The unadjusted prevalence (number of canagliflozin users who are patients with T1DM divided by total number of all existing canagliflozin users) and incidence (number of new canagliflozin users who are patients with T1DM divided by the number of all new users) of patients with T1DM in canagliflozin users will be calculated by year as well as overall. The linear trends of annual prevalence and incidence over the study period will be tested using a general linear regression model or the Joinpoint regression model if potential nonlinear trends are observed. Individual database-specific estimates will be combined per country as well as overall through meta-analysis.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

The Information System for Research in Primary Care (SIDIAP)

Data source(s), other

IQVIA Inc Belgium, IQVIA Inc Italy, IQVIA Inc Spain

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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