Sodium-glucose cotransporter-2 inhibitor initiation and the short-term risk of hospitalized acute kidney injury (SGLT2 inhibitors and short-term AKI)

First published: 27/04/2018

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/23747

EU PAS number

EUPAS23746

Study ID

23747

DARWIN EU® study

No

Study countries

United States

Study description

In response to a series of post-marketing safety reports linking sodium-glucose cotransporter-2 (SGLT2) inhibitors to AKI, the U.S. Food and Drug Administration enhanced renal-related warnings on the package inserts of all SGLT2 inhibitors in June 2016. However, subsequent investigations evaluating data from clinical trials and small-observational cohorts have found no such association. Given the rarity of AKI, these studies were likely under-powered to detect AKI-related safety signals.To further our understanding of the kidney-related risk-benefit profiles of SGLT2 inhibitors in the T2DM population, well-designed pharmacoepidemiologic studies are urgently needed. The proposed project will leverage the Truven Health MarketScan® research database to evaluate the association between SGLT2 inhibitor initiation and the risk of hospitalized AKI among commercially insured beneficiaries from the U.S.

Study status

Ongoing

Research institutions and networks

Institutions

University of North Carolina at Chapel Hill

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Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Primary lead investigator

Magdalene Assimon

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/04/2018

Actual: 27/04/2018

Study start date

Planned: 27/04/2018

Actual: 27/04/2018

Data analysis start date

Planned: 27/04/2018

Actual: 27/04/2018

Date of final study report

Planned: 27/04/2019

Sources of funding

- Other

More details on funding

Unfunded

Study protocol

SGLT2 inhibitor AKI protocol (version 1).pdf(437.52 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness
Drug utilisation

Main study objective:
Objective 1 = To describe the temporal trends of SGLT2 inhibitor use in cohort of commercially insured beneficiaries with T2DM from the U.S. Objective 2 = To evaluate the association between SGLT2 inhibitor initiation and the short-term risk of hospitalized AKI in in cohort of commercially insured beneficiaries from the U.S.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(A10BK) Sodium-glucose co-transporter 2 (SGLT2) inhibitors
Sodium-glucose co-transporter 2 (SGLT2) inhibitors
(A10BB) Sulfonylureas
Sulfonylureas

Medical condition to be studied
Type 2 diabetes mellitus
Acute kidney injury

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)

Special population of interest

Renal impaired

Hepatic impaired

Estimated number of subjects

300000

Study design details

Outcomes

The primary outcome of interest is hospitalized AKI.

Data analysis plan

For our outcomes study will will use an active comparator new-user study design. Cox proportional hazards models will be used to estimate hazard ratios (HRs) and their 95% confidence intervals (CIs) at each respective time point of interest (30-, 60- 90- and 180-days after new-use). In addition, Kaplan-Meier methods will be used to estimate risk differences (RDs) at each respective time point of interest (30-, 60- 90- and 180-days after new-use). The 95% CIs for RDs will be obtained using a non-parametric bootstrap based on 250 resamples. Across all analyses, inverse probability of treatment (IPT) weighting will be used for confounding control.

Data management

Data sources

Data source(s), other

Longitudinal Prescription Data - US

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