Incidence of phimosis and paraphimosis in patients treated with SGLT2 inhibitors

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/106883

EU PAS number

EUPAS106882

Study ID

106883

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

A cohort study aimed at estimating one-year and two-year incidence proportions of phimosis and paraphimosis among individuals who initiated treatment with an SGLT2 inhibitor.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andrei Barbulescu

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 10/07/2023

Actual: 10/07/2023

Study start date
Planned: 10/07/2023

Actual: 10/07/2023

Date of final study report
Planned: 31/08/2023

Actual: 08/09/2023

Sources of funding

- EMA

Study protocol

Final_Analysis_Plan--Phimosis__Paraphimosis__SGLT2i__Redacted_version_for_publication.pdf(292.55 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To estimate the incidence of phimosis and paraphimosis in male patients who initiated SGLT2 inhibitors (regardless of indication and restricted to a type-2

diabetes mellitus cohort) and also in type-2 diabetic male patients no exposed to SGLT2 inhibitors (background population).

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

Medical condition to be studied

Phimosis

Paraphimosis

Population studied

Short description of the study population

The study population included male patients with any identified phimosis/paraphimosis event initiated treatment with SGLT2 inhibitors from January 2022 to January 2023

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

10000

Study design details

Outcomes

Phimosis and paraphimosis

Data analysis plan

Eligible study participants were followed from study entry (i.e., initiation of an SGLT2 inhibitor in the treated cohorts or start of calendar year in the background cohort) until the first of: outcome event, death, loss to follow-up or the end of the study period. Crude incidence proportions were calculated as the ratio of: numerator: number of study participants who experienced the outcome event during follow-up denominator: number of patients at risk at the start of follow-up .To account for censoring during follow-up, incidence proportions (i.e., cumulative incidences) were also calculated using the product-limit method.

Documents

Study results

Final_Report--Phimosis__Paraphimosis__SGLT2i__Redacted_version_for_publication.pdf(419.14 KB)

Data management

Data sources

Data source(s)

IQVIA Disease Analyzer Germany

Disease Analyzer - OMOP

THIN® (The Health Improvement Network®)

IQVIA Medical Research Data - OMOP

Data sources (types)

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