Characteristics of patients initiating empagliflozin or other non-insulin glucose lowering drugs in the United Kingdom (Empa DUS in UK)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20835

EU PAS number

EUPAS14507

Study ID

20835

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Empagliflozin, a sodium glucose cotransporter 2 (SGLT-2) inhibitor, was launched in the United Kingdom (UK) in August 2014. It can be expected that patients initiating empagliflozin may differ in their characteristics from patients initiating other glucose lowering drugs (GLDs) that have been on the market longer (e.g. patients may have poorer glucose control). Therefore, the proposed study aims to characterize patients with T2DM in the UK initiating empagliflozin in terms of baseline characteristics, concomitant medications, and comorbidities compared to patients with T2DM initiating other SGLT-2 inhibitors or other non-insulin GLDs. Due to the mode of action, some patients taking empagliflozin have experienced weight loss in clinical trials. A theoretical possibility exists that empagliflozin may be used by patients without T2DM. Therefore, this study also aims to assess the potential off-label use of empagliflozin compared to other non-insulin GLDs.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Soulmaz Fazeli Farsani

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/10/2015

Actual: 09/10/2015

Study start date

Planned: 01/09/2016

Actual: 10/09/2016

Data analysis start date

Planned: 01/09/2016

Actual: 10/09/2016

Date of final study report

Planned: 30/11/2016

Actual: 04/11/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim GmbH

Study protocol

1245-0122-protocol-2016-08-11_Version 2.0_highlighted_geschwärzt.pdf(591.2 KB)

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe and compare the general characteristics of patients with a recorded diagnosis of T2DM starting empagliflozin in the UK to the characteristics of patients with a recorded diagnosis of T2DM initiating other medications in the SGLT-2 inhibitor class and other non-insulin GLDs.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10BA02) metformin

metformin

(A10BB) Sulfonylureas

Sulfonylureas

(A10BH) Dipeptidyl peptidase 4 (DPP-4) inhibitors

Dipeptidyl peptidase 4 (DPP-4) inhibitors

Medical condition to be studied

Diabetes mellitus

Population studied

Short description of the study population

Individuals in the UK CPRD who have initiated empagliflozin, other SGLT-2 inhibitors, or other noninsulin GLDs (metformin, sulfonylureas, DPP-4 inhibitors, GLP-1 agonists) during the study period which will start 01 August 2014 (the empagliflozin launch date in the UK) and end 01 September 2015.

Age groups

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)

Special population of interest

Other

Special population of interest, other

Diabetes mellitus patients

Estimated number of subjects

30000

Study design details

Outcomes

To describe and compare the general characteristics of patients with a recorded diagnosis of T2DM starting empagliflozin in the UK to the characteristics of patients with a recorded diagnosis of T2DM initiating other non-insulin GLDs, To assess the extent of off-label use by identifying the proportion of patients initiating empagliflozin or other non-insulin GLDs who do not have a recorded diagnoisis of T2DM

Data analysis plan

The analysis will be descriptive at baseline. Baseline patient characteristics will be tabulated for different exposure groups and results will be presented as means, standard deviations, medians, minimum, and maximum and interquartile range (IQR) for continuous variables, and as counts and percentages for categorical variables.

Documents

Study results

1245-0122-final-report_redacted_final.pdf(110.76 KB)

Data management

Data source(s)

Clinical Practice Research Datalink

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

Unknown