Observational single-cohort data base study of dapagliflozin utilisation in Europe (NA)

First published: 21/04/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS13199

Study ID

18553

DARWIN EU® study

No

Study countries

- Belgium
- France
- Germany
- Italy
- Spain
- United Kingdom

Study description

This drug utilization study is set up to describe the characteristics of European patients newly prescribed dapagliflozin by age, sex, dapagliflozin dose, country, selected co-morbidities, and selected concomitant medications.It will specifically describe dapagliflozin use in:• patients > 75 years-old,• combination use with loop diuretics or pioglitazone,• patients with a known history of moderate or severe renal impairment and in kidney failure,• patients lacking a diagnostic code indicating type 2 diabetes.This is an observational single-cohort data base study with descriptive data analyses among patients receiving dapagliflozin within electronic medical records in Europe. The study will describe the utilization pattern of dapagliflozin during the first 3.5 years after marketing authorization and launch in Europe, specifically in Belgium, France, Germany, Italy, Spain and United Kingdom.Will be included in the study all patients identified in the database(s) who newly received at least one dapagliflozin prescription during the study period. Data will be collected from IMS Health Longitudinal Patient Databases (LPDs) which come directly from physicians' EMR.A patient will be identified as newly exposed when he/she has at least one dapagliflozin prescription recorded in the study database(s).Outcomes include: Patient demographics: age, sex, country, Baseline history of type 2 diabetes, Baseline history of moderate or severe renal impairment, Concomitant medications at baseline and during dapagliflozin use.Follow-up will begin on the date a patient is first prescribed dapagliflozin, and it will continue until the end of study or discontinuation of dapagliflozin.In this study descriptive analyses of the data will be conducted.

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Joelle Asmar

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 19/03/2013

Study start date

Actual: 01/01/2013

Date of final study report
Planned: 12/10/2016

Actual: 15/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

mb102134-prot_Redacted.pdf (4.68 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)

Other study registration identification numbers and links

D1690R00006

Methodological aspects

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

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The main objective of the study is to describe the characteristics of patients newly prescribed dapagliflozin by age, sex, dapagliflozin dose, country, co-morbidities, and concomitant medications in all new users and the following subgroups: patients > 75 years-old, with combination use with loop diuretics or pioglitazone, with a history of renal impairment and patients not reported to have T2DM.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10BD15) metformin and dapagliflozin

metformin and dapagliflozin

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

All patients identified in the Cegedim database for at least one year prior to the first prescription and who newly received at least one dapagliflozin prescription during the study period.

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

Estimated number of subjects

7.109

Study design details

Data analysis plan

Descriptive statistics will be calculated to describe baseline characteristics among dapagliflozin initiators. These characteristics include age group, sex, initial dapagliflozin dose, country, BMI, eGFR, co-morbidities, concomitant medications, and available results of laboratory testing. We will also describe dapagliflozin use within and outside the labeled indication of type 2 diabetes.Qualitative variables will be described by frequencies and percentages. For each class, number of missing values will be presented. Quantitative variables will be described with number of observed data, mean, standard deviation, median, first and third quartiles, and number of missing values.In order to assess the impact of missing data, key variables (e.g. BMI and eGRF) will be checked by describing patients with and without missing values, respectively, regarding basic characteristics available for all or most patients, including age, gender, country, co-medication and co-morbidity.

Documents

Study results

study-mb102134-csr-final24mar_Redacted.pdf (1.25 MB)

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 source(s), other

LifeLink EMR FR, IMS LifeLink:Longitudinal Prescription Data-Spain, IMS LifeLink:Longitudinal Prescription Data - Bel

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