Effectiveness of SGLT2 Inhibitors in Patients With Heart Failure: Real-World Cohort Study.

First published: 03/09/2024

Last updated: 03/09/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000068

EU PAS number

EUPAS1000000068

Study ID

1000000068

DARWIN EU® study

No

Study countries

☐ France

Study description

This study will use real-world data from the French National Health Database SNDS spanning from 2021 to 2023 to evaluate the effectiveness of SGLT-2 inhibitors in heart failure. Participants will be identified based on their initial heart failure related hospitalization. Two groups will be established: one exposed to SGLT-2 inhibitors and one not exposed. Patients will be matched based on propensity scores. The study will assess outcomes including hospitalizations related to heart failure and overall mortality.

Study status

Planned

Research institutions and networks

Institutions

Toulouse University Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University Toulouse III

France

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Contact details

Study institution contact

Paul Gautier

Study contact

pgautier95@gmail.com

Primary lead investigator

Paul Gautier

Primary lead investigator

ORCID number:

0009-0008-9934-8432

Study timelines

Date when funding contract was signed

Planned: 01/01/2024

Actual: 01/01/2024

Study start date

Planned: 01/04/2024

Data analysis start date

Planned: 01/06/2024

Date of final study report

Planned: 01/09/2024

Sources of funding

- Other public funding (e.g. hospital or university)

More details on funding

P.G. received a grant from the Fédération Française de Cardiologie for the academic year 2023-2024.

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Cohort study based on administrative data (French National Health Database).

Main study objective:

The main objective of the study is to determine, in heart failure individuals, the effectiveness of gliflozins combined with standard heart failure medication compared to standard heart failure medication alone on the combined risk of hospitalization for heart failure and all-cause mortality.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

DAPAGLIFLOZIN

Name of medicine, other

Empagliflozin

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

DAPAGLIFLOZIN

EMPAGLIFLOZIN

Anatomical Therapeutic Chemical (ATC) code

(A10BK) Sodium-glucose co-transporter 2 (SGLT2) inhibitors

Sodium-glucose co-transporter 2 (SGLT2) inhibitors

(A10BK01) dapagliflozin

dapagliflozin

(A10BK03) empagliflozin

empagliflozin

Additional medical condition(s)

Heart Failure

Population studied

Short description of the study population

Patients from the database

- aged > 18 years

- with first heart failure related hospitalization between 2021 and 2023

- with no history of organ transplantation, renal chronic failure or cancer/hematologic disease prior to inclusion

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

270000

Study design details

Setting

Inclusion criteria:
Patients aged >18 years hospitalized between 2021 and 2023 for a first episode of heart failure.

Exclusion criteria:
Individuals hospitalized for heart failure in the 2 years preceding inclusion.
Individuals treated with left ventricular mechanical assistance or cardiac transplantation during the first hospitalization for heart failure.
Individuals with a history of organ transplantation, chronic renal failure or cancer/hematological disease before inclusion.
Individuals readmitted for any reason within 30 days following the index hospitalization.

Exposure:
Exposure will be defined according to a per-protocol model: individuals will be considered exposed if they receive a dispensing of empagliflozin or dapagliflozin within 30 days following discharge from hospital and will be censored in case of treatment discontinuation. Treatment discontinuation will be considered effective if there is a gap of more than 60 days between two dispensings. Individuals who have not received a dispensing of gliflozin within

the first 30 days following inclusion will be considered unexposed and will be censored on the date of first dispensing in case of treatment initiation.

Comparators

Standard of care in heart failure (ie. betablockers, ACE inhibitors, MRA inhibitors and sacubitril/valsartan)

Outcomes

Hospitalization for heart failure and all-cause mortality during follow-up.

Data analysis plan

Main analysis according to the per-protocol model. Development of a CTS (calendar time specific) propensity score with 1:1 matching using the nearest neighbor method. Survival analysis using the Kaplan-Meier method, estimation of relative risks using a Cox model.

Data management

Data sources

Data source(s)

Système National des Données de Santé (French national health system main database)

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