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

**First published:** 03/09/2024

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Study Planned

## Administrative details

**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

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Study contact

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**Primary lead investigator**

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Primary lead investigator

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# Study timelines

**Date when funding contract was signed**

Planned: 01/01/2024

Actual: 01/01/2024

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**Study start date**

Planned: 01/04/2024

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**Data analysis start date**

Planned: 01/06/2024

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**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

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**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

**Medicinal product name**

DAPAGLIFLOZIN

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**Medicinal product name, other**

Empagliflozin

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**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)

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**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.

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**Comparators**

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

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**Outcomes**

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

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**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

## 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)**

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