Impact of SGLT2i on Rates of Heart Failure Hospitalizations in France: an Interrupted Times Series

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000723

Study ID

1000000723

DARWIN EU® study

No

Study countries

☐ France

Study status

Ongoing

Research institutions and networks

Institutions

Toulouse University Hospital

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Institution

Contact details

Study institution 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: 25/07/2025

Actual: 25/07/2025

Study start date
Planned: 25/08/2025

Actual: 25/08/2025

Data analysis start date
Planned: 25/09/2025

Date of final study report
Planned: 25/10/2025

Sources of funding

- No external funding

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Study design:

This study is an interrupted time series between 2016 and 2024.

Main study objective:

The main objective of this study is to assess populational impact of SGLT2i release in France (April 2020) on rates of heart failure hospitalizations, in patients with history of heart failure.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Interrupted Time Series

Study drug and medical condition

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

DAPAGLIFLOZIN

EMPAGLIFLOZIN

Anatomical Therapeutic Chemical (ATC) code

(A10BK01) dapagliflozin

dapagliflozin

(A10BK03) empagliflozin

empagliflozin

Medical condition to be studied

Heart failure with midrange ejection fraction

Heart failure with preserved ejection fraction

Heart failure with reduced ejection fraction

Population studied

Short description of the study population

Patients > 18 years, with heart failure

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)

Special population of interest

Renal impaired

Special population of interest, other

Diabetes

Estimated number of subjects

650000

Study design details

Setting

Patients with history of heart failure will be included. HF will by defined by the following criteria :

1/ Hospitalization for HF in the past 5 years

2/ Hospitalization for HF complication in the past 5 years

3/ Hospitalization for other condition, with related diagnosis of HF in the past year

4/ Hospitalization for HF in rehabilitation care, in the past year

5/ Ongoing Long Term Disease reimbursement for HF

Intervention date will be set at the release of SGLT2i in France, which was on April 2020.

Comparators

This design has no comparator group.

Outcomes

Times series will be the following :

1/ Monthly rates of SGLT2i exposure (defined by at least one delievery of SGLT2i)

2/ Monthly rates of HHF (defined by unplanned hospitalization for HF)

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

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Unknown