Initiation of Sodium-Glucose Cotransporter 2 inhibitors after first hospitalization for heart failure: a population-based cohort study

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Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000378

EU PAS number

EUPAS1000000378

Study ID

1000000378

DARWIN EU® study

No

Study countries France

Study description

This study aims to describe SGLT-2i initiation after discharge from first heart failure hospitalization in France between 2021 and 2023.

Study status

Planned

Research institutions and networks

Institutions

Toulouse University Hospital

First published: 01/02/2024

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Institution

University Toulouse III

France

First published: 01/02/2024

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Educational Institution

Pharmacologie En Population cohorteS biobanqueS (PEPSS), Hopitaux de Toulouse France First published: 31/03/2022 Last updated: 01/07/2024 Institution Educational Institution Hospital/Clinic/Other health care facility ENCEPP partner

Contact details

Study institution contact

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Primary lead investigator

Paul Gautier

Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 01/11/2024

Actual: 01/11/2024

Study start date

Planned: 14/11/2024

Data analysis start date

Planned: 14/12/2024

Date of final study report

Planned: 01/02/2024

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

Cohort study of patients discharged from first hospitalization for heart failure between 2021 and 2023.

Main study objective:

Proportion of SGLT-2i initiation at 30 days after discharge.

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

Medical condition to be studied

Cardiac failure

Population studied

Short description of the study population

Patients > 18 years discharged from first hospitalization for heart failure between 2021 and 2023

Age groups

Adult and elderly population (≥18 years)

Special population of interest

Renal impaired

Special population of interest, other

Diabetes

Estimated number of subjects

300000

Study design details

Comparators

Not applicable.

Outcomes

SGLT-2i initiation in the 30 days following hospital discharge.

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

Yes			
Check compl	eteness		
Yes			
Check stabili	ty		
Yes			

Check logical consistency

Check conformance

Yes

Data characterisation

Data characterisation conducted

Not applicable