Effects of empagliflozin on cardiac remodeling and myocardial sympathetic nervous system in diabetic patients affected by chronic heart failure

First published: 21/01/2019

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Study Planned

Administrative details

EU PAS number

EUPAS27636

Study ID

27637

DARWIN EU® study

No

Study countries

Italy

Study description

Background. Heart failure (HF) patients often exhibit several comorbidities that contribute to affect prognosis. In particular, type 2 diabetes mellitus (DM) is common in HF with prevalence from 10 to 30% and adversely influences long-term morbidity and mortality of symptomatic and asymptomatic HF patients. The results of a recent study on the effects of the anti-diabetic drug empagliflozin, reported unattended and substantial favorable effects on cardiovascular outcomes, and in particular a striking reduction of HF hospitalization, that was consistently demonstrated in patients with and without HF at baseline. The mechanisms behind these effects are unknown and many potential contributors have been advocated, including effects on plasma volume, arterial stiffness, sympathetic nervous system modulation and cardiac remodeling.Objectives. Aim of the present study is to investigate the mechanisms underlying the beneficial effects of empagliflozin on cardiovascular outcomes in diabetic patients affected by chronic HF with reduced left ventricular ejection fraction. In particular, the primary endpoint is to assess the effect of empagliflozin on left ventricular remodeling and function and on biomarkers of HF hemodynamic status. Secondary endpoint is to assess the effects of empagliflozin on myocardial sympathetic nervous system activity.Methods. Prospective cohort study. Patients will receive empagliflozin according to diabetologists' prescription. Endpoints will be evaluated by in each study procedure by two investigators blinded to personal patients' data and treatment allocation. On the first study day patients will undergo clinical examination, echocardiography and I123MIBG Imaging to assess myocardial adrenergic status. Then patients will start the prescribed treatment and after 6-9 months of follow-up will repeat the baseline study procedures to assess the effects of empagliflozin on study outcomes.

Study status

Planned

Research institutions and networks

Institutions

University of Naples Federico II

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Pasquale Perrone Filardi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/12/2018

Study start date

Planned: 03/06/2019

Date of final study report
Planned: 03/06/2021

Sources of funding

- Other

More details on funding

Federico II University of Naples

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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

The primary endpoint is to assess the effect of empagliflozin on left ventricular remodeling and function and on biomarkers of HF hemodynamic status. Secondary endpoint is to assess the effects of empagliflozin on myocardial sympathetic nervous system activity.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

EMPAGLIFLOZIN

Medical condition to be studied

Chronic left ventricular failure

Type 2 diabetes mellitus

Population studied

Age groups

- Adults (18 to < 46 years)

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Estimated number of subjects

34

Study design details

Outcomes

The primary endpoint is to assess the effect of empagliflozin on left ventricular remodeling and function and on biomarkers of HF hemodynamic status. Secondary endpoint is to assess the effects of empagliflozin on myocardial sympathetic nervous system activity.

Data analysis plan

Prospective cohort study. Patients will receive empagliflozin according to diabetologists’ prescription. Endpoints will be evaluated by in each study procedure by two investigators blinded to personal patients’ data and treatment allocation.

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 sources (types)

Spontaneous reports of suspected adverse drug reactions

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