A non-interventional study of the effectiveness and safety outcomes in patients with heart failure and preserved ejection fraction (HFpEF) initiating Jardiance in China: A sub-study of the post-arketing study of Jardiance among patients with heart failure in China

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/106764

EU PAS number

EUPAS106763

Study ID

106764

DARWIN EU® study

No

Study countries

China

Study status

Planned

Research institutions and networks

Institutions

Heart Failure Medical Union of the National Center for Cardiovascular Diseases (HFMU-NCCD)

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Institution

Contact details

Study institution contact

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Primary lead investigator

Yanwen Xiong

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/11/2023

Study start date
Planned: 30/06/2025

Date of final study report
Planned: 01/06/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

The effectiveness and safety outcomes among Chinese hospitalized HFpEF patients initiating Jardiance in the real-world setting will be described to complement the evidence from the EMPEROR-Preserved trial. Primary Objective: To describe the incidence of composite outcome of cardiovascular (CV) death or hospitalization for heart failure (HHF) in HFpEF patients initiating Jardiance in China.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Single-arm

Study drug and medical condition

Name of medicine

JARDIANCE

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

3000

Study design details

Outcomes

Incidence of the composite outcome of HHF (the first HHF after the index date) or CV death, Incidence of CV death -Incidence of the HHF (the first HHF after the index date) -Death from any cause

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Data analysis plan

Baseline characteristics of the HFpEF patients as listed in the section “covariates” will be described among patients who initiate Jardiance in the HFMU-NCCD data. To evaluate the difference of baseline characteristics between the RCT and this study, patients’ baseline characteristics in this study will be compared against East Asia and China patients in the treatment (Jardiance) and placebo group in the EMPEROR-Preserved trial (1245.110). The primary analysis will be an as-treated analysis. For all the study outcomes, the incidence rate and 95% confidence intervals will be calculated. The sensitivity analysis will be done which restricts to patients in regions that are well covered by the CDC mortality surveillance, to investigate the influence of mortality surveillance data quality on the results.

Data management

Data sources

Data source(s), other

Heart Failure Medical Union of the National Center for Cardiovascular Diseases (HFMU-NCCD) China

Data sources (types)

Disease registry

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