# 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

**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: 31/01/2028

**Study start date**
Planned: 31/01/2028

**Date of final study report**
Planned: 31/12/2028

# 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

# Other study registration identification numbers and links

1245-0313

NCT07047508

# 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)

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

**Medicinal product name**

JARDIANCE

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

EMPAGLIFLOZIN

## Population studied

**Short description of the study population**

Patients with heart failure and preserved ejection fraction (HFpEF) initiating Jardiance

**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**

3.000

## 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

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**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