

# Non-interventional study of the effectiveness and safety of Jardiance in patients with heart failure (HF) of reduced ejection fraction (HFrEF) compared to guideline-recommended non- SGLT2i therapy regimens in China: A sub-study of the postmarketing study of Jardiance among patients with heart failure in China

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Study

Planned

## Administrative details

### EU PAS number

EUPAS106700

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### Study ID

106701

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## DARWIN EU® study

No

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### Study countries

☐ China

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### 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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Study 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

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### **Study start date**

Planned: 30/06/2025

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### **Date of final study report**

Planned: 01/03/2026

## 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

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

Not applicable

## Methodological aspects

**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Main study objective:**

To provide the effectiveness and safety evidence in patients with HFrEF initiating Jardiance in real clinical practice in a larger Chinese population. Primary Objective: To compare the risk of the composite outcome of Cardiovascular (CV) death or HHF in HFrEF patients initiating Jardiance with propensity score (PS) matched HFrEF patients initiating guideline-recommended non-SGLT2i medications.

## Study Design

**Non-interventional study design**

Cohort

## 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)

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## **Estimated number of subjects**

5000

# **Study design details**

## **Outcomes**

Time from the index date to the first HHF or CV death, -Time from the index date to CV death -Time from the index date to the first HHF -Total number of HHFs at 30 days after the index date -Total number of HHFs at 90 days after the index date -Total number of HHFs at 1 year after the index date -Time from the index date to all-cause death

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## **Data analysis plan**

Matching: All collected baseline patient characteristics, including drug class distribution, in each exposure group (including the comparability between Jardiance and each comparator drug class) will be tabulated and described before and after PSM matching. If there still are covariates not meeting the 0.1 threshold after matching, they will be adjusted in the regression model described below. Risk estimation: for each of the time to event outcomes, multivariate adjusted hazard ratio and corresponding 95% confidence intervals (CI) will be estimated in the PS-matched cohorts using Cox regression model. Kaplan-Meier curves will also be produced. Total number of HHFs at 30, 90 days

and 1 year after the index date will be analysed using Negative Binomial regression. Rate ratio and corresponding 95% CI will be estimated using the PS-matched cohorts.

## 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), 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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No