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

PURI

https://redirect.ema.europa.eu/resource/106701

EU PAS number

EUPAS106700

Study ID

106701

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: 01/03/2026

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

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)

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)

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

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