A regulatory requirement non-interventional study to monitor the safety and effectiveness of Jardiance® (empagliflozin, 10mg) in Korean patients with chronic heart failure (NYHA class II-IV)

First published: 09/12/2021

Last updated: 06/03/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47613

EU PAS number

EUPAS44641

Study ID

47613

DARWIN EU® study

No

Study countries

Korea, Republic of

Study description

To monitor the safety profile and effectiveness of JARDIANCE® in Korean patients with chronic heart failure (NYHA class II-IV)

Study status

Ongoing

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Hyerim Hwang

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/06/2022

Actual: 20/06/2022

Study start date
Planned: 30/06/2022

Actual: 28/07/2022

Data analysis start date
Planned: 01/10/2025

Date of interim report, if expected
Planned: 22/01/2024

Actual: 19/01/2024

Date of final study report
Planned: 22/02/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

[Eng]1245-0276-hfref-nis-protocol_v3.0_Redacted.pdf(438.35 KB)

Protocol Amendment_10 Jan 2025_1245-0276_V8.0__Redacted.pdf(825.71 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

1245-0276

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Study design:

Observational prospective, single arm, non-interventional, open-label, multi-centre study

Main study objective:

To monitor the safety profile and effectiveness of JARDIANCE® in Korean patients with chronic heart failure (NYHA class II-IV)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

JARDIANCE 10 MG - FILM-COATED TABLET

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

EMPAGLIFLOZIN

Anatomical Therapeutic Chemical (ATC) code

(A10BK03) empagliflozin

empagliflozin

Medical condition to be studied

Cardiac failure chronic

Population studied

Short description of the study population

Korean adult patients with chronic heart failure (NYHA class II-IV)

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

600

Study design details

Setting

1. Selection criteria

1-1. Inclusion

- Patients who have started at first time on Jardiance® in accordance with the approved label in Korea
- Chronic heart failure (NYHA class II-IV)
- Age ≥19 years at enrolment
- Patients who have signed on the data release consent form

1-2. Exclusion criteria:

- Patients with previous exposure to Jardiance®
- Known allergy or Hypersensitivity to active ingredients empagliflozin or to any of the excipients
- Patients with type 1 diabetes or with prior history of diabetic ketoacidosis (DKA)

- Patient with renal impairment with eGFR < 20 mL/min/1.73 m2
- Patients with rare hereditary conditions of galactose intolerance, the Lapp lactase deficiency or glucose galactose malabsorption
- Patient who are pregnant or are nursing or who plan to become pregnant while in the trial
- Patients for whom empagliflozin is contraindicated according local label of Jardiance

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Comparators

Not applicable

Outcomes

The primary objective of this study is to monitor the safety profile and effectiveness of JARDIANCE® in Korean patients with chronic heart failure (NYHA class II-IV) in a routine clinical setting. The secondary objective of this study is to monitor the occurrence of hospitalization for heart failure(first and recurrent) or cardiovascular death within 12 weeks and/or 24 weeks from baseline.

Data analysis plan

1) Analysis of demographic data: Demographic data and the health status of subjects for the safety evaluation will be analysed descriptively. For continuous data, the number of patients, mean, standard deviation, minimum value, maximum value, and median will be described, while for categorical data, frequency will be shown.
2) Safety analysis: In the safety assessment population, the number of subjects to whom AE occurred and the number of AEs will be calculated. Also, the incidence proportion of AEs will be estimated with its 95% confidence interval.
3) Effectiveness analysis: Mean, standard deviation, minimum value, maximum value, and median of changes in HbA1 or FPG (if available), eGFR (if available),

Body weight, and blood pressure, which were measured at the last visit versus baseline, should be presented, and analyzed using paired t-test.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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