Post Marketing Surveillance on Long Term Drug Use of JARDIANCE® Tablets in Patients with chronic heart failure in Japan (PMS of JARDIANCE in CHF)

First published: 22/11/2021

Last updated: 18/12/2025

Study Finalised

Administrative details

EU PAS number

EUPAS44340

Study ID

46998

DARWIN EU® study

No

Study countries

☐ Japan

Study description

Study objective is to investigate the safety and effectiveness of long-term daily use of JARDIANCE® Tablets in patients with chronic heart failure under real-world use.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sakurako Watanabe

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 17/03/2022

Actual: 13/12/2021

Study start date
Planned: 01/04/2022

Actual: 01/04/2022

Data analysis start date
Planned: 01/08/2024

Date of final study report
Planned: 30/06/2025

Actual: 18/03/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd., Eli Lilly Japan K.K.

Study protocol

1245-0286_protocol_redacted.pdf (1.4 MB)

1245-0286-non-interventional-study-protocol_ver.4.0_Redacted.pdf (400.62 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

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Cohort study

Non-interventional, single arm study based on newly collected data. Patients were observed for up to 52 weeks after start of the treatment with JARDIANCE® Tablets or until discontinuation of administration.

Main study objective:

Study objective is to investigate the safety and effectiveness of long-term daily use of JARDIANCE® Tablets in patients with chronic heart failure under real-world use.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

JARDIANCE

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

Cardiac failure chronic

Population studied

Short description of the study population

Inclusion criteria

- Patients with CHF who are prescribed with JARDIANCE® Tablets in Japan.
- Patients who have never been treated with Empagliflozin (including treatment for type 2 diabetes mellitus [T2DM]) before enrolment.

Exclusion criteria

- None

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

1200

Study design details

Setting

Sites throughout entire country were equally listed according to the size of the hospitals or general clinics at which JARDIANCE® Tablets were available for prescription. Planned number of sites: Approximately 200 Sites (including cardiovascular [CV] internal medicine A medical representative explained the objective and design of this study
to investigators at each study site and concluded a written contract with the head of the study site (e.g., hospital director). This study was conducted in 146 centres in Japan.
Study period: April 2022 – Jun 2024
Enrollment period: April 2022 – Mar 2023

Outcomes

Primary outcome:
- Incidence of adverse drug reactions (ADRs) (focus on hypoglycaemia, the events relevant to volume depletion, influence of ketone body increased / ketoacidosis, renal impairment)

Secondary outcome:
- Incidence of all-cause death
- Incidence of CV death
- Incidence of hospitalizations for heart failure (HF)

Further outcome:
Other safety outcomes;
- Incidences of serious adverse events (SAEs)
- Time to all-cause death, CV death and hospitalization for HF
- Change from baseline in eGFR over time
- Baseline characteristics

Data analysis plan

Analyses are descriptive in nature, including confidence intervals.

Documents

Study results

1245-0286_Synopsis.pdf (348.44 KB)

Study publications

Link to full article "Safety and effectiveness of empagliflozin in Japanese pat...

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

Patients’ data were collected by electronic CRF on Electronic Data Capture (EDC) system

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