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: 27/08/2024

Study Ongoing

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

Ongoing

Research institutions and networks

Institutions

Boehringer Ingelheim

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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: 31/05/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

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

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

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

Name of medicine

JARDIANCE

Medical condition to be studied

Cardiac failure

Population studied

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

Outcomes

Incidence of adverse drug reactions (ADR), Incidence of all-cause death Incidence of CV death Incidence of hospitalizations for heart failure

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Data analysis plan

Analyses are descriptive in nature, including confidence intervals.

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 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