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

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