Post Marketing Surveillance in Japan on Long Term Drug Use of JARDIANCE® Tablets in Patients with type 2 Diabetes Mellitus (Japanese JARDIANCE PMS, long term)

First published: 23/05/2015

Last updated: 21/10/2026

Study Finalised

Administrative details

EU PAS number

EUPAS9786

Study ID

43727

DARWIN EU® study

No

Study countries

Japan

Study description

Study to investigate the safety and efficacy of long-term daily use of JARDIANCE® Tablets in Japanese patients with type 2 diabetes mellitus.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

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Institution

Multiple centres: 999 centres are involved in the study

Contact details

Study institution contact

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Study contact

zzCDMJP_PV_PMS@boehringer-ingelheim.com

Primary lead investigator

Hisaka Saisho

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/07/2014

Actual: 25/07/2014

Study start date

Planned: 01/06/2015

Actual: 12/06/2015

Data analysis start date

Planned: 01/06/2015

Actual: 12/06/2015

Date of final study report

Planned: 31/10/2021

Actual: 07/10/2021

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

1245-0094_CTP_final-rule_Redacted.pdf (284.16 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

1245.94

NCT02489942

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Cohort study. Non-interventional, prospective, observational, single arm based on new data collection

Main study objective:

To investigate the safety and efficacy of long-term daily use of JARDIANCE® Tablets in Japanese patients with type 2 diabetes mellitus

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Non-interventional, prospective, observational, single arm

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

Type 2 diabetes mellitus

Population studied

Short description of the study population

Male and female Japanese patients with type 2 diabetes mellitus who have never been treated with JARDIANCE® Tablets before the enrolment.

Age groups

- 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)

Special population of interest

Other

Special population of interest, other

Type 2 diabetes mellitus patients

Estimated number of subjects

3.000

Study design details

Setting

Sites throughout entire country were equally listed according the size of the hospitals or general clinics at which JARDIANCE® Tablets were available for prescription. Patients were selected by using the continuous investigation system. This study was conducted in 1,103 centers in Japan. Study period: June 2015 – November 2020. Enrollment period: June 2015– May 2017

Outcomes

Incidence of adverse drug reactions, Change from baseline in HbA1c to the last-observation on treatment. Change from baseline in Fasting plasma glucose to the last- observation on treatment

Data analysis plan

Descriptive statistics will be summarized for safety and efficacy. A mixed model repeated measures analysis will be performed for HbA1c over time. Incidence of adverse drug reactions Change from baseline in HbA1c to the last- observation on treatment. Change from baseline in Fasting plasma glucose to the last-observation on treatment.

Documents

Abstract of study report

1245-0094_Synopsis.pdf (211.18 KB)

Data management

Data sources

Data source(s), other

Patients data were gathered by electronic Case Report Form (CRF) on electronic data capture (EDC)

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