

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)

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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

Hisaka Saisho zzCDMJJP_PV_PMS@boehringer-ingelheim.com

Study contact

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: 11/10/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Study protocol

[1245_94_protocol_synopsis.pdf](#)(109.12 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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Primary 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

Name of medicine

JARDIANCE

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

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)

Special population of interest

Other

Special population of interest, other

Type 2 diabetes mellitus patients

Estimated number of subjects

3000

Study design details

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.

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