Post Marketing Surveillance in Japan on Drug Use of JARDIANCE® Tablets in Elderly Patients with type 2 Diabetes Mellitus (Japanese PMS, elderly patients)

First published: 17/02/2015

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Study Finalised

Administrative details

EU PAS number

EUPAS8663

Study ID

20374

DARWIN EU® study

No

Study countries

☐ Japan

Study description

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

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Multiple centres: 500 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Rie Ikeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/07/2014

Actual: 25/07/2014

Study start date

Planned: 23/02/2015

Actual: 24/02/2015

Data analysis start date

Planned: 23/02/2015

Actual: 24/02/2015

Date of final study report

Planned: 26/08/2017

Actual: 25/07/2017

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_98_protocol_synopsis.pdf(107.95 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:

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 daily use of JARDIANCE® Tablets in Japanese elderly 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 elderly patients (age 65 and over) with type 2 diabetes mellitus who have never been treated with JARDIANCE® Tablets before the enrolment and start taking JARDIANCE® Tablets within 3 months after launch in Japan.

Age groups

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

Diabetes mellitus patients

Estimated number of subjects

720

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

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

Unknown