A regulatory requirement non interventional study to monitor the safety and effectiveness of JARDIANCE® (empagliflozin 10mg, 25mg) in Korean patients with type 2 diabetes mellitus (JARDIANCE® rPMS in Korean patients with T2DM)

First published: 31/05/2016

Last updated: 18/12/2025

Study Finalised

Administrative details

EU PAS number

EUPAS13627

Study ID

24002

DARWIN EU® study

No

Study countries

Korea, Republic of

Study description

To monitor the safety profile and effectiveness of Empagliflozin in Korea patients with type 2 diabetes mellitus in a routine clinical practice setting

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

DaeWook Lee

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 10/06/2016

Actual: 05/07/2016

Study start date
Planned: 30/07/2016

Actual: 11/08/2016

Data analysis start date
Planned: 11/06/2020

Date of final study report
Planned: 11/11/2020

Actual: 27/01/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

1245-0116_Protocol_SAP_redacted.pdf (574.63 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

If ‘other’, further details on the scope of the study

Safety monitoring

Data collection methods:

Primary data collection

Study design:

This is a single arm study with JARDIANCE®. JARDIANCE® will be prescribed according to the local label and at the discretion of the treating physician.

Main study objective:

To monitor the safety profile and efficacy of JARDIANCE® (empagliflozin, 10mg, 25mg) in Korean patients with type 2 diabetes mellitus in a routine clinical practice setting

Study Design

Non-interventional study design

Cohort

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

Inclusion criteria:

• Patients who have started at first time on JARDIANCE® in accordance with the approved label in Korea

• Age ≥19 years at enrolment

• Patients who have signed on the data release consent form

Exclusion criteria:

• Known hypersensitivity to empagliflozin or any of its excipients

• Patients with type 1 diabetes or for the treatment of diabetic ketoacidosis (DKA)

• Patients with persistent eGFR<60 mL/min/1.73 m2 , end stage renal disease or on dialysis

• Patients with rare hereditary conditions of galactose intolerance, the Lapp lactase deficiency or glucose-galactosemalabsorption

• Patients for whom empagliflozin is contraindicated according local label of JARDIANCE®

Age groups

- 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

3000

Study design details

Setting

Patients will be managed according to the local practice guidelines. The choice of treatment will be solely at the discretion of the participating physician. JARDIANCE® will be administered according to the approved label in Korea.

Outcomes

1) PRIMARY OBJECTIVETo monitor the safety profile and effectiveness of Empagliflozin in Korea patients with type 2 diabetes mellitus in a routine clinical practice setting, 2) SECONDARY OBJECTIVE(1) Change from baseline in HbA1c after 12 weeks and/or 24 weeks of treatment(2)Occurrence of treat to target effectiveness response that is an HbA1c under treatment of < 7% after 12 weeks and/or 24 weeks of treatment(3) Occurrence of relative effectiveness response (HbA1c lowering by at least 0.5% after 12 weeks and/or 24 weeks)

Data analysis plan

1)Analysis of demographic data:Demographic data and the health status of subjects for the safety evaluation will be analysed descriptively.For continuous data, mean, standard deviation, minimum value, and maximum value will be described, while for categorical data, frequency will be shown.2)Safety analysis: In the safety assessment population, the number of subjects to whom AE occurred and the number of AEs will be calculated. Also, the incidence proportion of AEs will be estimated with its 95%confidence interval.3)Efficacy analysis: Mean,standard deviation,minimum value,maximum value,and median of changes in glycosylated hemoglobin and fasting plasma glucose,body weight,and blood pressure, which were measured at the last visit versus baseline, should be presented, and if there is difference before administration versus after administration should be analyzed using paired t-test. The number and percentage of subjects for final efficacy evaluation

Documents

Study results

1245-0116_Synopsis.pdf (458.09 KB)

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