A regulatory requirement non interventional study to monitor the safety and effectiveness of JARDIANCE DUO® (empagliflozin/metformin, 5/500mg, 5/850mg, 5/1000mg, 12.5/500mg, 12.5/850mg, 12.5/1000mg) in Korean patients with type 2 diabetes mellitus (JARDIANCE DUO® rPMS)

First published: 25/06/2018

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS24004

Study ID

26822

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study description

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

Study status

Ongoing

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

JiEun Lee

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/09/2018

Actual: 21/08/2018

Study start date
Planned: 31/10/2018

Actual: 08/10/2018

Data analysis start date
Planned: 31/03/2020

Date of final study report
Planned: 30/11/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

1276-0039

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

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

Study drug and medical condition

Name of medicine, other

JARDIANCE DUO

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

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

600

Study design details

Outcomes

To monitor the safety profile and effectiveness of JARDIANCE DUO in Korean patients with type 2 diabetes mellitus in a routine clinical practice setting, The secondary objective of this study is to monitor the effectiveness of JARDIANCE DUO by evaluation of the change from baseline after 12 weeks and/or 24 weeks in the glycosylated hemoglobin (HbA1c), fasting plasma glucose (FPG), body weight, blood pressure (SBP, DBP) and the final effectiveness evaluation at the end of the last visit in Korean T2DM patients.

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 analysisAmong the subjects of safety evaluation, the number of subjects with adverse event incurred and the number of adverse events incurred should be calculated, and the incidence rate of adverse events and the 95% confidence interval should be presented.3) Effectiveness analysisMean,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.

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