A regulatory non-interventional study to monitor the safety and efficacy of JARDIANCE® (Empagliflozin 10 mg) in Korean patients with Chronic Kidney Disease (CKD)

First published: 24/10/2023

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Study Ongoing

Administrative details

EU PAS number

EUPAS107293

Study ID

107340

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Hyelin Lee

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2024

Actual: 29/03/2024

Study start date

Planned: 29/03/2024

Actual: 29/03/2024

Date of final study report

Planned: 27/02/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Korea

Study protocol

[Eng]1245-0323-onis-protocol-final-v2-EUPAS.pdf (654.31 KB)

1245-0323-protocol-v3-final_Redacted.pdf (1021.66 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

Study type:

Non-interventional study

Main study objective:

To monitor the safety profile and efficacy of JARDIANCE® in Korean patients with CKD in routine clinical practice

Study drug and medical condition

Name of medicine

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

Chronic kidney disease

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

250

Study design details

Outcomes

The primary outcomes are the safety outcomes calculated as the incidence of AEs, SAEs, non-SAEs, ADRs, serious ADRs, unexpected AEs, AESIs, etc. Change in UACR from baseline after 12 weeks and/or 24 weeks of treatment

Data analysis plan

All statistical analyses will be explorative in nature.
Participant characteristics will be reported using measures of central tendency (e.g. mean, median) and variance (standard deviation, quartiles) for continuous variables and using frequencies and percentages for count data. Frequency of safety events will be reported using frequencies and incidence with 95% confidence interval (CI).
The changes of the efficacy outcomes from baseline will be compared in an exploratory sense via 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

The source data will be captured from the medical records of the patients who have consented to data release.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

No

Check completeness

No

Check stability

No

Check logical consistency

No

Data characterisation

Data characterisation conducted

No