Post Marketing Surveillance on Long Term Use of JARDIANCE® Tablets in Patients with Chronic Kidney Disease in Japan

First published: 29/07/2024

Last updated: 19/10/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000279

Study ID

1000000279

DARWIN EU® study

No

Study countries

Japan

Study status

Ongoing

Contact details

Study institution contact

Akiko Ito akiko.ito@boehringer-ingelheim.com

Study contact

akiko.ito@boehringer-ingelheim.com

Primary lead investigator

Akiko Ito

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/08/2024

Study start date

Planned: 01/09/2024

Actual: 22/10/2024

Date of final study report

Planned: 30/04/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.

Study protocol

observational and non-interventional study protocol 1245-0340_V1.0_redacted.pdf (406.85 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

Other study registration identification numbers and links

1245-0340

NCT06527846

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Cohort study

Non-interventional, single arm study based on newly collected data Patients will be observed for up to 52 weeks after the start of the treatment with JARDIANCE® Tablets or until discontinuation of administration.

Main study objective:

Study objective is to investigate the safety and effectiveness of long-term daily use of JARDIANCE® Tablets in patients with CKD under real-world use.

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

Chronic kidney disease

Population studied

Short description of the study population

Inclusion criteria-

- Patients with CKD who are prescribed JARDIANCE® Tablets for CKD according to the current Japanese package insert and who provided written informed consent prior to enrolment in this study.

- Patients who have never been treated with Empagliflozin (including treatment for T2DM

and CHF) before enrolment.

Special population of interest

Renal impaired

Estimated number of subjects

1.000

Study design details

Outcomes

-Kidney disease progression (defined as incidence of ESKD, a sustained decline in eGFR to <10 mL/min/1.73m2, renal death, or a sustained decline of ≥40% in eGFR from baseline)

-Cardiovascular death

-All cause death

-Hospitalization for heart failure

-Change from baseline in eGFR 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.

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