A regulatory requirement non-interventional study to monitor the safety and effectiveness of Glyxambi (empagliflozin/linagliptin, 10/5mg, 25/5mg) in Korean patients with type 2 diabetes mellitus

First published: 06/12/2021

Last updated: 24/02/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47610

EU PAS number

EUPAS44579

Study ID

47610

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study description

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

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

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Primary lead investigator

Hyerim Hwang

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/12/2021

Study start date

Planned: 31/03/2022

Actual: 26/03/2022

Date of final study report

Planned: 30/06/2023

Actual: 02/08/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

Eng Esgliteo PMS_1275-0028-protocol_v5.0_28Oct2022_clean_Redacted.pdf
(483.39 KB)

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

1275-0028

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Study design:

Prospective, Non-interventional, Multi-centre, Single-country Study

Main study objective:

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

Study drug and medical condition

Name of medicine

GLYXAMBI 10 MG + 5 MG - FILM-COATED TABLET

GLYXAMBI 25 MG + 5 MG - FILM-COATED TABLET

Name of medicine, other

'Esgliteo' is regional brand name in Korea.

Study drug International non-proprietary name (INN) or common name

EMPAGLIFLOZIN

LINAGLIPTIN

Anatomical Therapeutic Chemical (ATC) code

(A10BD19) linagliptin and empagliflozin

linagliptin and empagliflozin

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

Audilt T2DM Patients

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 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

Setting

1. Patients diagnosed with type 2 diabetes mellitusin Korea

2. ESGLITEO® is administered as an adjunct to diet and exercise therapy to improve glycaemic controlin patients with type 2 diabetes mellitus

3. Inclusion Criteria:

-Patients who have startedtreatment withESGLITEO® for the first time in accordance with the label approvedin Korea

-Patients aged 19 yearsor olderat enrollment

-Patients who have signed the Informed Consent Form for the Use of Personal Information

4. Exclusion Criteria:

-Patients with previous exposure to ESGLITEO®

-Patients with hypersensitivity to the active ingredients of this drug, empagliflozin and/or linagliptin, orany of the excipients of this drug

-Patients with type 1 diabetes or diabetic ketoacidosis

-Patients with estimated Glomerular Filtration Rate (eGFR) < 45mL/min/1.73m2, end stage renal disease, or patients on dialysis

-Patients for whom the use of empagliflozin/linagliptinis contraindicated according to the prescribinginformationof
ESGLITEO®

Comparators

Not applicable

Outcomes

To monitor the safety profile and effectiveness of Esgliteo in Korean patients with type 2 diabetes mellitus in a routine clinical practice setting, Change from baseline in HbA1c after 12 weeks and/or 24 weeks of treatment

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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) Analysis of Safety Among 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 frequency of adverse events and the 95% confidence interval should be presented. 3) Analysis of Effectiveness Mean, standard deviation, minimum value, maximum value, and median of changes in

glycosylated hemoglobin(HbA1c) and fasting plasma glucose(FPG), weight, and blood pressure, which were measured at the last visit versus baseline, should be presented, and if there is a difference before administration versus after administration should be analyzed using paired t-test.

Summary results

During this re-examination period, the incidence of the Adverse Event (AE) reported in 616 subjects for safety evaluation was 3.41% (21/616, 26 cases). Among these, the incidence of Adverse Drug Reactions (ADRs), in which a causal relationship with this drug could not be ruled out, was 0.65% (4/616, 4 cases), and all were found to be non-serious ADRs. The incidence of Serious Adverse Event (SAE) was found to be 0.49% (3/616, 4 cases), and there was no Serious Adverse Drug Reaction (SADR) for which a causal relationship with this drug could not be ruled out. Unexpected Adverse Event (UAE) was found to be 1.46% (9/616 subjects, 10 cases), and among these, Unexpected Adverse Drug Reaction (UADR), in which a causal relationship with the drug could not be ruled out, was found to be 0.16% (1/616 subjects, 1 case).

Adverse Event of Special Interest (AESI) was found to be 0.16% (1/616 subjects, 1 case), and there were no AEs that led to discontinuation of the drug.

The results of the final effectiveness evaluation at 12 weeks after administration in 190 subjects for effectiveness evaluation showed that57.89% (110/190 subjects) were ‘Improved’, 39.47% (75/190subjects) were ‘Unchanged’, and 2.63% (5/190subjects) were ‘Aggravated’. When ‘Improved’ was classified as ‘effective’ and ‘Unchanged’ or ‘Aggravated’ as ‘ineffective’, the effective rate of ESGLITEO® was 57.89% (110/190 subjects).

According to this post-marketing surveillance for ESGLITEO®, no unusual tendency to be carefully observed regarding safety and efficacy was found, and no significant new information that could affect risk versus benefit assessment was identified.

Documents

Study report

1275-0028-study-report-v3-0_02Aug2024_Final_Redacted.pdf(164.87 KB)

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

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Not applicable