

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

In-vivo Bioequivalence Study of Empagliflozin/Linagliptin 25/5 mg Kharazmi Pharma Co Tablets of The Test Drug in Compared with The Reference Drug (GLYXAMBI® Tab 25/5 mg. Beohringer Ingelheim Germany) In Healthy Volunteers

Protocol summary

Study aim

In-vivo Bioequivalence Study of Empagliflozin/Linagliptin 25/5 mg Kharazmi Pharma Co Tablets of The Test Drug in Compared with The Reference Drug (GLYXAMBI® Tab 25/5 mg. Beohringer Ingelheim Germany) In Healthy Volunteers

Design

Bioequivalence study, crossover, single-blinded, 24 healthy volunteers. Simple randomization was used for randomization

Settings and conduct

The study is a single-blinded (Volunteers), cross-over and fasting, and on two series of healthy volunteers. The study will be done in two periods (72h). The interval between these two periods is two week. In the first round of the study, the candidates were divided into two groups the first group received a test tablet and the second group received a brand tablet. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. Sampling is performed in Radin laboratory in Tabriz.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: General Health (Liver, Heart, and Kidney), Body Mass Index (18-28), Informed consent, Age (18-55 years old) Exclusion criteria: Smoking, History of cardiovascular disease, History of liver and kidney disease, Alcohol and drug addiction, History of allergy to Empagliflozin or Linagliptin

Intervention groups

Intervention group 1: The Reference Drug (GLYXAMBI® Tab 25/5 mg. Beohringer Ingelheim Germany)
Intervention group 2: Empagliflozin/Linagliptin 25/5 mg Kharazmi Pharma Co Tablets of The Test Drug

Main outcome variables

Maximum drug concentration, Time to reach maximum

drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N97**

Registration date: **2024-02-21, 1402/12/02**

Registration timing: **prospective**

Last update: **2024-02-21, 1402/12/02**

Update count: **0**

Registration date

2024-02-21, 1402/12/02

Registrant information

Name

Javad Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3661 4125

Email address

shokri.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-20, 1403/02/01

Expected recruitment end date

2025-04-21, 1404/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In-vivo Bioequivalence Study of Empagliflozin/Linagliptin 25/5 mg Kharazmi Pharma Co Tablets of The Test Drug in Compared with The Reference Drug (GLYXAMBI® Tab 25/5 mg. Beohringer Ingelheim Germany) In Healthy Volunteers

Public title

Bioequivalence Study of Empagliflozin/Linagliptin 25/5 mg Kharazmi Pharma Co

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

General Health (Liver, Heart, and Kidney) Body Mass Index (18-28) Informed consent Age (18-55 years old)

Exclusion criteria:

Smoking History of cardiovascular disease History of liver and kidney disease Alcohol and drug addiction History of allergy to Empagliflozin or linagliptin

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **2**

Randomization (investigator's opinion)

Randomized

Randomization description

En Each candidate is assigned a number from 1 to 24. The numbers are written on a plastic ball, poured into a container, and mixed. The balls are then removed randomly from the container and divided in 2 groups of 12 test (A) and reference (B) drug recipients, then in the second phase, groups A and B will be cross-referenced to the test and drug recipients.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blinded clinical trial (volunteers). Test and Originator brand's tablets are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test dosage form.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences ethics committe

Street address

No. 48, Ferdows street, Ferdowsi Sq.

City

Tabriz

Province

East Azarbaijan

Postal code

5167874434

Approval date

2024-01-14, 1402/10/24

Ethics committee reference number

IR.TBZMED.REC.1402.788

Health conditions studied

1

Description of health condition studied

This study is performed on healthy volunteers and drug concentration in plasma is determined.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug plasma concentration

Timepoint

0, 0.5, 1, 1.5, 2, 2.5, 0.3, 3.5, 4.0, 6.0, 8.0, 10, 12, 24, 48 , 72h after drug administration

Method of measurement

Liquid Chromatography Mass-Mass

Secondary outcomes

1

Description

Time to reach maximum plasma concentration

Timepoint

After intervention

Method of measurement

Time to reach the maximum drug concentration in plasma is recorded.

2

Description

Extent of absorption

Timepoint

After intervention

Method of measurement

Calculation of area under curve of concentration -time

Intervention groups**1****Description**

Intervention group: single dose, one oral tablet GLYXAMBI® 25/5 mg manufactured by Boehringer as a reference product. after washout period, the volunteers receive Empagliflozin/Linagliptin 25/5 mg Kharazmi Pharma Co

Category

Treatment - Drugs

2**Description**

Intervention group: Single dose, one oral Empagliflozin/Linagliptin 25/5 mg Kharazmi Pharma Co as test product. after washout period, the volunteers receive GLYXAMBI® Tab 25/5 mg Boehringer Ingelheim Germany

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Radin laboratory

Full name of responsible person

Javad Shokri

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No.22, first floor, Moalem st., Abureihan St

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kharazmi Pharmaceutical Co

Full name of responsible person

Peiman Tarhami

Street address

No 115 ,kharazmi pharmaceutical DE ,Jalal ST

,Shahrak aesteqlal ,Tehran

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1389716512

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+98 21 4454 5413

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info@kharazmipharm.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kharazmi Pharmaceutical Co

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Javad Shokri

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

En These data are as secure between researchers and related industries.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available