

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Bioequivalence study of Empagliflozin/Linagliptin 25/5 mg tablet manufactured by Actover Co. versus originator brand in healthy volunteers in fasting condition

Protocol summary

Study aim

Bioequivalence Study of Empagliflozin/Linagliptin 25/5 mg tablet (Glypover 25/5) manufactured by Actover Co. versus originator brand (Glyxambi) manufactured by Boehringer company

Design

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

Settings and conduct

The study is a single-blinded, cross-over and fasting, and on two series of healthy volunteers. The study will be done in Tabriz, in Radin laboratory in two (96h) periods. The interval between these two periods is 5 weeks. In the first round of the study, the candidates are divided into two groups and the first group receives a test tablet and the second group receives 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.

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, Alcoholism and Narcoticism, History of allergy to Empagliflozin/Linagliptin

Intervention groups

Intervention group 1: Glyxambi 25/5 mg tablet as a reference Intervention group 2: Glypover 25/5 mg manufactured by Actover Co. as a test

Main outcome variables

Maximum drug concentration, Time to reach maximum drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200623047902N36**

Registration date: **2024-01-26, 1402/11/06**

Registration timing: **prospective**

Last update: **2024-01-26, 1402/11/06**

Update count: **0**

Registration date

2024-01-26, 1402/11/06

Registrant information

Name

Elham Ghasemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6696 5196

Email address

ghasemian@zistdaru.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of Empagliflozin/Linagliptin 25/5 mg tablet manufactured by Actover Co. versus originator brand in healthy volunteers in fasting condition

Public title

Bioequivalence study of Empagliflozin/Linagliptin 25/5 mg tablet

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 Alcoholism and Narcoticism History of allergy to Empagliflozin/Linagliptin

Age

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

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

People in the mentioned age group are invited to participate through the advertisement. People are then checked for health and healthy volunteers are identified. Each candidate is assigned a number from 1 to 24. The numbers are written on a plastic ball and poured into a container and mixed. The balls are then removed randomly from the container. The first 12 no.s are considered as (first sequence: Actover Co.'s medicine) and the second 12 no.s are considered as (second sequence: originator brand recipient). The volunteers don't have any information about taking the test drug or brand drug

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

Research Ethics Committees of Tabriz University of Medical Sciences

Street address

Research and technology deputy,3rd floor, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Province

Tehran

Postal code

5165665931

Approval date

2024-01-14, 1402/10/24

Ethics committee reference number

IR.TBZMED.REC.1402.797

Health conditions studied

1

Description of health condition studied

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

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug concentration in plasma

Timepoint

pre-dose, 0.25, 0.50, 0.75, 1.00, 1.50, 2.00, 2.50, 3.00, 4.00, 6.00, 8.00, 12.0, 24.0, 36.0, 48.0, 72.0 and 96.0 h after drug administration

Method of measurement

Liquid chromatography-MASS-MASS (LC- Mas/Mas)

Secondary outcomes

1

Description

Time to reach maximum drug concentration in plasma

Timepoint

After intervention

Method of measurement

Time to reach the maximum drug concentration is recorded.

2

Description

Extent of drug 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 25/5mg manufactured by Boehringer as a reference product. after the washout period, the volunteers receive Glypover 25/5mg tablet manufactured by Actover Co.

Category

Treatment - Drugs

2

Description

Intervention group: Single dose, Glypover 25/5mg tablet manufactured by Actover Co. as a test product. after the washout period, the volunteers receive Glyxambi 25/5 mg manufactured by Boehringer.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Radin laboratory

Full name of responsible person

Javad Shokri

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

5154995671

Phone

+98 914 313 5843

Email

Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Actover Co.

Full name of responsible person

Reza Karimi

Street address

No. 58, 8th St, Gisha

City

Tehran
Province
Tehran
Postal code
1446863914
Phone
+98 26 3476 0314
Email
info@actoverco.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Actover 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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Elham Ghasemian

Position

Visiting professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Islamic Azad university of Damghan, Cheshme Ali bolivar, Saadi square

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3671637856

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Fax

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Ghasemian_elham@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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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

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