Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)
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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

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Tabriz

Province

East Azarbaijan

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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

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Province

Tehran

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1446863914

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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

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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