Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Bioequivalence study of Empagliflozin/Linagliptin 25/5 mg manufactured by faran pharmed Co.versus originator brand GLYXAMBI® 25/5 mg manufactured by Boehringer Co in fasting condition in healthy volunteers

Protocol summary

Study aim

Bioequivalence study of Empagliflozin/Linagliptin 25/5 mg manufactured by faran pharmed Co.versus originator brand GLYXAMBI® 25/5 mg manufactured by Boehringer Co in fasting condition 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, 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 2 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 Empaglifluzin&Linagliptin

Intervention groups

Intervention group: Empagliflozin/Linagliptin 25/5 mg manufactured by faran pharmed Co Intervention group: GLYXAMBI® 25/5 mg manufactured by Boehringer Co

Main outcome variables

Maximum drug concentration, Time to reach maximum drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N96**
Registration date: **2024-02-17, 1402/11/28**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-17, 1402/11/28**
Update count: **0**

Registration date

2024-02-17, 1402/11/28

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

2024-02-11, 1402/11/22

Expected recruitment end date

2025-02-10, 1403/11/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Bioequivalence study of Empagliflozin/Linagliptin 25/5 mg manufactured by faran pharmed Co.versus originator brand GLYXAMBI® 25/5 mg manufactured by Boehringer Co in fasting condition in healthy volunteers

Public title
Bioequivalence study of Empagliflozin/Linagliptin 25/5 mg

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 Linagliptin&Empagliflozin

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**

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: Faran pharmed'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
Tabriz University of Medical Sciences ethics committe

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

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Approval date
2024-01-14, 1402/10/24

Ethics committee reference number
IR.TBZMED.REC.1402.786

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 , 72 after drug administration

Method of measurement
Liquid Chromatography Mass-Mass

Secondary outcomes

1

Description
En Time to reach maximum plasma concentration

Timepoint
En After intervention

Method of measurement
En Time to reach the maximum drug concentration in plasma is recorded.

2

Description
En Extent of absorption
Timepoint
En After intervention
Method of measurement
En Calculation of area under curve of concentration -time

Intervention groups

1

Description
Intervention group: single dose, one oral GLYXAMBI® 25/5 mg manufactured by Boehringer Co as a reference product. after the washout period, the volunteers receive JARLINO Tab. 25/5 mg) tablet Faran pharmed Co.
Category
Treatment - Drugs

2

Description
Intervention group: Single dose, JARLINO Tab. 25/5 mg) tablet Faran pharmed Co. as a test product. after the washout, the volunteers receive GLYXAMBI® 25/5 mg manufactured by Boehringer Pharmaceuticals.
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
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East Azarbaijan
Postal code
5154995671
Phone
+98 914 313 5843
Email
shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
شرکت فاران فارمد
Full name of responsible person
Parsa Sirat
Street address
unit 1, No.32, Niroy entezami street, Attar square, Vanak square
City
Tehran
Province
Tehran
Postal code
1994767611
Phone
+98 21 5794 1000
Email
info@faranpharmed.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
شرکت فاران فارمد
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
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Other areas of specialty/work
Medical Pharmacy
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No 4, 10th Ave. Boostan Street, Roshdieh
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Person responsible for scientific

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Person responsible for updating data

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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