Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Bioequivalence study of Empagliflozin/ Linagliptin10/5 mg (JARLINO 10/5 mg) manufactured by Faran pharmed versus originate brand GLYXAMBI® Tab 10/5 mg. manufactured by Beohringer Ingelheim Germany in fasting condition in healthy volunteers

Protocol summary

Study aim
Bioequivalence study of Empagliflozin/ Linagliptin10/5 mg (JARLINO 10/5 mg) manufactured by Faran pharmed versus originator brand GLYXAMBI® Tab 10/5 mg. manufactured by Beohringer Ingelheim Germany in fasting condition in healthy volunteers

Design
Bioequivalence study, crossover, single-blinded, on 24 healthy volunteers. Simple randomization will be 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 72 our periods. The interval between these two periods is two weeks. In the first round of the study, the candidates will be divided into two groups. The first group will receive a test tablet and the second group will receive a brand tablet. In the second round, the first group will receive a brand tablet and the second group will receive a test tablet. The 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 of 18-28, Informed consent, Age of 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: Empagliflozin/ Linagliptin10/5 mg (GLYXAMBI® Tab 10/5 mg) manufactured by Beohringer Ingelheim Germanyas as reference. Intervention group 2: Empagliflozin/ Linagliptin10/5 mg (JARLINO 10/5 mg) manufactured by Faran pharmed Co. as 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: **IRCT20200105046010N100**
Registration date: **2024-03-01, 1402/12/11**
Registration timing: **prospective**

Last update: **2024-03-01, 1402/12/11**
Update count: **0**

Registration date
2024-03-01, 1402/12/11

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
Bioequivalence study of Empagliflozin/ Linagliptin10/5 mg (JARLINO 10/5 mg) manufactured by Faran pharmed versus originate brand GLYXAMBI® Tab 10/5 mg. manufactured by Beohringer Ingelheim Germany in fasting condition in healthy volunteers

Public title
Bioequivalence study of Empagliflozin/ Linagliptin10/5 mg

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
General Health (Liver, Heart, and Kidney) Body Mass Index 18-28 Informed consent Age of 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**
More than 1 sample in each individual
Number of samples in each individual: **32**
Blood sample

Randomization (investigator's opinion)
Randomized

Randomization description
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 taken out 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 originate brand's medicine are taken out 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.1402.789

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 h 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: First, one oral tablet of GLYXAMBI® Tab 10/5 mg manufactured by Beohringer is prescribed as a reference product. after the 72 h washout period, one oral tablet of JARLINO 10/5 mg manufactured by Faran pharmed as a test product is prescribed.

Category

Treatment - Drugs

2

Description

Intervention group: First, one oral tablet of JARLINO 10/5 mg manufactured by Faran pharmed as a test product is prescribed. after the 72h washout period, one oral tablet of GLYXAMBI® 10/5 mg manufactured by Beohringer is prescribed as a reference product.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Radin laboratory

Full name of responsible person

Javad Shokri

Street address

First floor, No.22, Moalem street, Abureihan street

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5154995671

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Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faran Pharmed company

Full name of responsible person

Parsa Sirat

Street address

Unit 1, No.32, Niroy-e-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

Faran Pharmed company

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
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