Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Bioequivalence study of Empagliflozin/Metformin12.5/1000 mg (EMZIP® 12.5/1000 mg) manufactured by Faran pharmed versus originator brand SYNJARDY® 12.5/1000 mg manufactured by Boehringer Co in fasting condition in healthy volunteers

Protocol summary

Study aim
Bioequivalence study of Empagliflozin/Metformin12.5/1000 mg (EMZIP® 12.5/1000 mg) manufactured by Faran pharmed versus originator brand SYNJARDY® 12.5/1000 mg manufactured by Boehringer 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 (Volunteers), cross-over and fasting, and on two series of healthy volunteers. The study will be done in two periods (48h). The interval between these two periods is a 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. In the second round, the first group received a brand tablet and the second group received 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 (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/Metformin

Intervention groups
Intervention group 1: Empagliflozin/Metformin12.5/1000 mg (SYNJARDY® 12.5/1000 mg) manufactured by Boehringer as a reference Intervention group 2: Empagliflozin/Metformin12.5/1000 mg (EMZIP® 12.5/1000 mg) manufactured by Faran pharmed 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: **IRCT20200105046010N93**
Registration date: **2024-02-11, 1402/11/22**
Registration timing: **prospective**

Last update: **2024-02-11, 1402/11/22**
Update count: **0**

Registration date
2024-02-11, 1402/11/22

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

2024-02-20, 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/Metformin12.5/1000 mg (EMZIP® 12.5/1000 mg) manufactured by Faran pharmed versus originator brand SYNJARDY® 12.5/1000 mg manufactured by Boehringer Co in fasting condition in healthy volunteers

Public title

Bioequivalence study of Empagliflozin/Metformin12.5/1000 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 Empagliflozin/Metformin

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: **2**

Blood sample

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. People are randomly placed in one of the two study groups with the help of a random number table and receive the intervention related to the same group. 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 medicine 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.1402.792

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, 3, 3.5, 4, 6, 8, 10, 12, 24, 48h 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 Empagliflozin/ Metformin 12.5/1000 mg (SYNJARDY® 12.5/1000 mg) manufactured by Boehringer Co as a reference product. after the washout period, the volunteers receive Empagliflozin/Metformin12.5/1000 mg (EMZIP® 12.5/1000 mg) manufactured by Faran pharmed.

Category

Treatment - Drugs

2

Description

Intervention group: Single dose, Empagliflozin/Metformin12.5/1000 mg (EMZIP® 12.5/1000 mg) manufactured by Faran pharmed as a test product. after the washout, the volunteers receive Empagliflozin/Metformin12.5/1000 mg (SYNJARDY® 12.5/1000 mg) manufactured by Boehringer Co

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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Postal code

5154995671

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+98 914 313 5843

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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, Nirue entezami st., 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

Industry

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