Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

In-vivo Bioequivalence Study of Empagliflozin/Metformin 5/500 mg FC. Tablets of The Test Drug (JARINOMET® 5/500 mg Tab. Kharazmi Pharma, Iran) in Compared with The Reference Drug (SYNJARDI® 5/500 mg. Boehringer Ingelheim Germany) In Iranian Healthy Volunteers

Protocol summary

Study aim

In-vivo Bioequivalence Study of Empagliflozin/Metformin 5/500 mg FC. Tablets of The Test Drug (JARINOMET® 5/500 mg Tab. Kharazmi Pharma, Iran) in Compared with The Reference Drug (SYNJARDI® 5/500 mg. Boehringer Ingelheim Germany) In Iranian 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. 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 or Metoformin

Intervention groups

Intervention group 1:The Reference Drug (SYNJARDI® 5/500 mg. Boehringer Ingelheim Germany) Intervention group 2: Empagliflozin/Metformin 5/500 mg FC. Tablets of The Test Drug

Main outcome variables

Maximum drug concentration, Time to reach maximum drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N95**
Registration date: **2024-02-16, 1402/11/27**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-16, 1402/11/27**
Update count: **0**

Registration date

2024-02-16, 1402/11/27

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
In-vivo Bioequivalence Study of Empagliflozin/Metformin 5/500 mg FC. Tablets of The Test Drug (JARINOMET® 5/500 mg Tab. Kharazmi Pharma, Iran) in Compared with The Reference Drug (SYNJARDI® 5/500 mg. Boehringer Ingelheim Germany) In Iranian Healthy Volunteers

Public title
Bioequivalence Study of Empagliflozin/Metformin 5/500 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 Alcohol and drug addiction History of allergy to Empagliflozin orMetoformin
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
En 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 removed randomly from the container and divided in 2 groups of 12 test (A) and reference (B) drug recipients, then in the second phase, groups A and B will be cross-referenced to the test and drug recipients.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a single-blinded clinical trial (volunteers). Kharazmi's Empagliflozin and Originator brand capsules 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.1402.793

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، 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: Intervention group: Intervention group: single dose, one oral tablet SYNJARDI® Tab 5/500 mg manufactured by Boehringer as a reference product. after washout period, the volunteers receive JARINOMET® Tab. 5/500 mg tablet manufactured by Kharazmi Co.
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group: Single dose, one oral Empagliflozin/Metformin 5/500 mg manufactured by Kharazmi company as test product. after washout period, the volunteers receive(SYNJARDI® 5/500 mg. Boehringer Ingelheim Germany
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
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5154995671
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+98 914 313 5843
Email
shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kharazmi Pharmacy
Full name of responsible person
Peymn Tarrahomi
Street address
No. 115 Kharazmi Pharmacy Deadlock, Shahid Gholamreza Jalal St., Esteghlal Town, Tehran
City
Tehran
Province
Tehran
Postal code
1389716512
Phone
+98 21 4454 5413
Email
info@kharazmipharm.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kharazmi Pharmacy
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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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
En 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