

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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 or Metoformin

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

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No.22, first floor, Moalem st., Abureihan St

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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 scientific inquiries

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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