

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Bioequivalence study of Empagliflozin 25 mg tablet manufactured by Kharazmi company versus originator brand in healthy volunteers in the fasted condition

Protocol summary

Study aim

Bioequivalence Study of Empagliflozin (Jaribet) 25 mg manufactured by Kharazmi company versus originator brand (Jardiance) manufactured by Boehringer

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 (48h). The interval between these two periods is one week. The candidates were divided into two groups in the first round of the study. the first group receives a test tablet and the second group receives 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. These steps are 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.

Intervention groups

Intervention group 1: Jardiance 25 mg tablet as a reference Intervention group 2: Jaribet 25 mg 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: **IRCT20200105046010N83**

Registration date: **2023-09-26, 1402/07/04**

Registration timing: **prospective**

Last update: **2023-09-26, 1402/07/04**

Update count: **0**

Registration date

2023-09-26, 1402/07/04

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

2023-10-07, 1402/07/15

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of Empagliflozin 25 mg tablet

manufactured by Kharazmi company versus originator brand in healthy volunteers in the fasted condition		Deputy of research and technology, 3rd floor, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street	
Public title	Bioequivalence study of Empagliflozin 25 mg tablet	City	Tabriz
Purpose	Treatment	Province	East Azarbaijan
Inclusion/Exclusion criteria		Postal code	5165665931
Inclusion criteria:	General Health (Liver, Heart, and Kidney) Body Mass Index (18-28) Informed consent Age (18-55 years old)	Approval date	2023-09-04, 1402/06/13
Exclusion criteria:	Smoking History of cardiovascular disease History of liver and kidney disease Alcohol and drug addiction History of allergy to Empagliflozin	Ethics committee reference number	IR.TBZMED.REC.1402.456
Age	From 18 years old to 55 years old	Health conditions studied	
Gender	Both	1	
Phase	Bioequivalence	Description of health condition studied	
Groups that have been masked		This study is performed on healthy volunteers.	
	Participant	ICD-10 code	
Sample size	Target sample size: 24	ICD-10 code description	
Randomization (investigator's opinion)	Randomized	Primary outcomes	
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 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.	1	
Blinding (investigator's opinion)	Single blinded	Description	
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	The concentration of the drug in blood	
Placebo	Not used	Timepoint	
Assignment	Crossover	0, 0.5, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 24 and 48 h after drug administration.	
Other design features		Method of measurement	
Secondary Ids	empty	Liquid Chromatography Mass-Mass	
Ethics committees		Secondary outcomes	
1		1	
Ethics committee		Description	
Name of ethics committee	Tabriz University of Medical Sciences ethics committee	Time to reach maximum blood concentration	
Street address		Timepoint	
		After intervention	
		Method of measurement	
		The time to reach the maximum drug concentration in blood 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 tablet
25mg(Jardiance) manufactured by Boehringer, as a
reference product

Category

Treatment - Drugs

2

Description

Intervention group: Single dose, one oral Jaribet 25 mg
tablet manufactured by Kharazmi company as a test
product

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, Azadi alley, Moalem st., Abureihan
St

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Tabriz

Province

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5154995671

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+98 914 313 5843

Fax

Email

shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

kharazmi company

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 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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**Person responsible for scientific
inquiries**

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Person responsible for updating data

Contact

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Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
No 4, 10th Ave. Boostan Street, Roshdieh
City
Tabriz

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