

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Bioequivalence study of Empagliflozin 5/Metformin 500 mg tablet in healthy male volunteers using crossover design

Protocol summary

Study aim

Determination of bioequivalence in fasting state for Empagliflozin/Metformin tablet

Design

The clinical trial has control and test groups with crossover, randomized design, without blinding. Twenty-four healthy male volunteers will participate randomly in the study as two twelve-person study groups. Each volunteer will receive a single dose of drug in two periods. To randomly assign participants into two groups, the lottery method will be used.

Settings and conduct

After oral administration of one Empagliflozin/Metformin tablet, the blood samples will be collected in predetermined time intervals up to 72 hours. The samples will be stored in freezer -4 degrees centigrade until analysis. The concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector. The study will be performed in Faculty of Pharmacy, Tabriz University of Medical Sciences. This study will be conducted without blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (in terms of Liver, Heart and Kidney); Age (18-59 years old); Being male. Non-inclusion criteria: Smoking; History of cardiovascular, liver and kidney disease; Alcohol and drug addiction; History of drug allergy.

Intervention groups

Intervention group will receive a single oral dose of test product (Empagliflozin/Metformin tablet of Sobhan) and Control group will receive a single dose of reference product (Empagliflozin/Metformin tablet of Sofar, Italy). Blood samples will be taken for 72 hours at the mentioned time points and the plasma will be stored in freezer until analysis. In both groups, breakfast and lunch will be served two and six hours after drug administration, respectively)

Main outcome variables

Drug plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210519051345N31**

Registration date: **2023-07-13, 1402/04/22**

Registration timing: **prospective**

Last update: **2023-07-13, 1402/04/22**

Update count: **0**

Registration date

2023-07-13, 1402/04/22

Registrant information

Name

Parvin Zakeri-Milani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 8801

Email address

pzakeri@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-22, 1402/04/31

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Street address Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishabouri street., Golgasht street
Scientific title Bioequivalence study of Empagliflozin 5/Metformin 500 mg tablet in healthy male volunteers using crossover design	City Tabriz
Public title Investigating the in vivo bioequivalence of Empagliflozin /Metformin tablet	Province East Azarbaijan
Purpose Other	Postal code 51664-14766
Inclusion/Exclusion criteria Inclusion criteria: General Health (in terms of Liver, Heart and Kidney) Age between 18 to 59 years Being male Exclusion criteria: Smoking History of cardiovascular disease, liver and kidney disease Alcohol and drug addiction History of drug allergy	Approval date 2023-06-26, 1402/04/05
Age From 18 years old to 59 years old	Ethics committee reference number IR.TBZMED.REC.1402.269
Gender Both	Health conditions studied 1 Description of health condition studied In the present study, the products will be administered to healthy volunteers.
Phase Bioequivalence	ICD-10 code ICD-10 code description
Groups that have been masked <i>No information</i>	Primary outcomes 1 Description Plasma concentration of drug
Sample size Target sample size: 24	Timepoint At intervals between half and 72 hours after drug administration
Randomization (investigator's opinion) Randomized	Method of measurement HPLC (High performance liquid chromatography)
Randomization description To randomly assign participants in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope. Numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period.	Secondary outcomes empty
Blinding (investigator's opinion) Not blinded	Intervention groups 1 Description Intervention group: Intervention group will receive a single oral dose of test product (Empagliflozin/Metformin tablet manufactured by Sobhan Co.) in fasted state. Blood samples will be collected for 72 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively.
Blinding description Placebo Not used	Category Treatment - Drugs
Assignment Crossover	2 Description Control group: Control group will receive a single oral dose of reference product (Empagliflozin/Metformin tablet manufactured by Sofar Co.) in fasted state. Blood
Other design features	
Secondary Ids empty	
Ethics committees 1 Ethics committee Name of ethics committee Biomedical Research Committe, Tabriz University of Medical Sciences	

samples will be collected for 72 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faculty of Pharmacy Tabriz University of Medical Sciences

Full name of responsible person

Parvin Zakeri-Milani

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Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaboori st., Golgasht st.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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3rd Floor; central building number 2; Tabriz University of Medical Science; Daneshgah street

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Sobhan Pharmaceutical 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

Parvin Zakeri-Milani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable