Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Study of bioequivalence of 25 mg Empagliflozin tablets in healthy volunteers after single dose oral administration

Protocol summary

Study aim
Determination of plasma concentration of 25 mg Empagliflozin generic product of Zist Arvand Pharmed Company and 25 mg Jardiance Reference Product

Design
This study is a bioequivalence phase of clinical trial with control and cross over groups which is double-blinded and randomized and will be performed on 24 healthy subjects including 12 in control group and 12 in intervention group. For randomization, simple and restricted random allocation law is used.

Settings and conduct
This study is carried out at Shahid Beheshti School of Pharmacy, which has been the site of many similar studies. After receiving the drug orally , blood samples are taken from the volunteers at different times and the plasma concentration of the drug is measured by LC mass. In this double-blind study, volunteers, personnel and responsible physician is unaware for the type of drug and only the person responsible is aware of the type of drug. To ensure blinding, the drugs are removed from the box and both types are similar in appearance.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Healthy volunteers aged 18 to 50 years Exclusion criteria: History of liver, kidney and cardiovascular diseases that can affect drug clearance from body, History of taking any medication in the last two weeks, Creatinine above 2

Intervention groups
Intervention group: Oral intake of 25 mg Empagliflozin generic product of Zist Arvand Pharmed Company with one dose and evaluation of plasma concentration up to 48 hours in the blood of healthy volunteers Control group: Oral intake of 25 mg Jardiance reference product of Boehringer ingelheim with one dose and evaluation of plasma concentration up to 48 hours in the blood of healthy volunteers

Main outcome variables
Maximum plasma concentration of the drug

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210201050197N5**
Registration date: **2022-06-01, 1401/03/11**
Registration timing: **prospective**

Last update: **2022-06-01, 1401/03/11**
Update count: **0**

Registration date
2022-06-01, 1401/03/11

Registrant information
Name
Azadeh Haeri
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 8820 0212
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a_haeri@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-20, 1401/03/30

Expected recruitment end date
2022-07-21, 1401/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Study of bioequivalence of 25 mg Empagliflozin tablets in healthy volunteers after single dose oral administration

Public title
Bioequivalence of Empagliflozin
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy volunteer Age_18-50 year
Exclusion criteria:
History of liver, kidney and cardiovascular diseases that can affect drug clearance from body History of taking any medication in the last two weeks Creatinine above 2
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize in this study, simple and restricted random allocation rule will be used. This method represents a large block for the total sample size, meaning that the balance in the number of people assigned to each group will be achieved at the end. For this purpose, first, 24 candidates who meet the inclusion criteria will be selected. Then, 12 lotteries for the intervention group and 12 lotteries for the control group will be placed inside a lottery container. Then, randomly, each of these 24 individuals will take a lottery out of the container without replacement and deliver the lottery to the project officer and the allocation of the group to the individual will be determined (the person, physician and nurse responsible are not aware of the allocation of the group to the individual). In the second phase of the study, the person in the control group will be transferred to the intervention group and vice versa.
Blinding (investigator's opinion)
Double blinded
Blinding description
Volunteers and study physician are not aware of what products they have received at any time. Since the drug is removed from its box and blister and give to the volunteers, they will not know the type of medicine. The new drug are similar to the reference drug in terms of color, smell, flavor and consistency and all the apparent properties so that participants do not know the type of drug.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University
Street address
No:2660, Faculty of Pharmacy, Shahid beheshti university of medical scineces, Nyayesh complex, Valiasr st.
City
Tehran
Province
Tehran
Postal code
1996835113
Approval date
2021-09-21, 1400/06/30
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1400.135

Health conditions studied

1

Description of health condition studied
Determination of plasma concentration of Empagliflozin 25 mg pharmaceutical product
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Maximum plasma concentration of the drug
Timepoint
Before intervention and 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 12, 24, 32, 48 hours after intervention
Method of measurement
liquid chromatography-mass (LC-MS) device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, 12 volunteers receive a 25 mg Empagliflozin tablet made by Zist Arvand Pharmed Company. After 48 hours, blood samples will be taken from the volunteers and plasma concentration of the drug will be measured by liquid chromatography. Each time, 5 cc blood samples are taken from volunteers. Then these 12 volunteers will enter the control group after one week.

Category

Other

2

Description

Control group: In this group, 12 volunteers receive 25 mg Jardiance tablet made by Boehringer ingelheim company. After 48 hours, blood samples will be taken from the volunteers and plasma concentration of the drug will be measured by liquid chromatography. Each time, 5 cc blood samples are taken from volunteers. Then these 12 volunteers will enter the intervention group after one week.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azadeh Haeri

Street address

No:2660, Faculty of Pharmacy, Shahid beheshti university of medical scineces, Nyayesh complex, Valiasr st.

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Phone

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a_haeri@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

5th Floor, Bldg No.2 SBMU, Arabi abbas Ave, Yaman Blvd, Chamran Blvd

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azadeh Haeri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No 2660, School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University, Niayesh building, Valiasr Ave

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person
Azadeh Haeri

Position
Associate professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Position
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Latest degree
Ph.D.

Other areas of specialty/work
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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
Undecided - It is not yet known if there will be 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