

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparative bioequivalence study of the Empagliflozin 10 mg Tablets manufactured by Zist Arvand Pharmed Pharmaceutical Company

Protocol summary

Study aim

Demonstration of bioequivalence of Empagliflozin tablet 10 mg of Zist arvand pharmed Co. with Jardiance® tablet manufactured by Boehringer Ingelheim after single dose administration.

Design

Single dose, randomized and crossover bioequivalence study of Empagliflozin tablet 10 mg by Zist arvand pharmed Co. with Jardiance® (Boehringer Ingelheim) in 24 healthy male volunteers in two groups.

Settings and conduct

Study place and the place for blood sample analysis are the Drug Applied Research Center affiliated to Tabriz University of Medical Science, respectively. 24 healthy male volunteers will receive one 10 mg Empagliflozin tablets test or reference in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 7 days, If the first sequence receives Iranian medicine, they will receive brand medicine. Blood samples will be taken from all participants before and after receiving the drug at 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 12, 24, 36, and 48 hours after dosing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male subjects in the age range of 18-60 years and BMI (Body Mass Index) of 18-30.

Exclusion criteria: Subjects with Blood Pressure \leq 90/60 mm/Hg or BP \geq 140/90 mm/Hg. Any evidence of impairment of renal, hepatic, cardiac, lung or gastrointestinal function or a history of tuberculosis, epilepsy, asthma, diabetes, psychosis or glaucoma and regular smoker.

Intervention groups

Intervention group 1: Empagliflozin tablet 10 mg by Zist arvand pharmed Co. is the test product. Intervention group 2: Jardiance® (Boehringer Ingelheim) is the reference product. In each period, 12 of 24 subjects will be given single dose of this product. After the washout period, the volunteers are placed in the opposite group.

Main outcome variables

Peak Plasma Concentration (Cmax); Area under the concentration-time curve (AUC).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N38**

Registration date: **2022-08-02, 1401/05/11**

Registration timing: **prospective**

Last update: **2022-08-02, 1401/05/11**

Update count: **0**

Registration date

2022-08-02, 1401/05/11

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 2700

Email address

molavif@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-20, 1401/06/29

Expected recruitment end date

2022-11-20, 1401/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of the Empagliflozin 10 mg Tablets manufactured by Zist Arvand Pharmed Pharmaceutical Company

Public title
Study of absorption and elimination rate of Empagliflozin tablets 10 mg in comparison with Empagliflozin brand tablets (Jardiance®).

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The weight limit of each volunteer should be between 60 and 100 kg. All volunteers must be non-smokers. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed. Candidates who have consented to the consent form.

Exclusion criteria:
Known hypersensitivity or idiosyncratic reaction to Empagliflozin or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two weeks before dosing.

Age
From **18 years** old to **60 years** old

Gender
Male

Phase
Bioequivalence

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomly assign people 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 after entering the study, and 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 the both groups will change for the second period.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Science

Street address

Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-10-24, 1400/08/02

Ethics committee reference number

IR.TBZMED.REC.1400.702

Health conditions studied

1

Description of health condition studied

Bioequivalence study

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Peak Plasma Concentration (Cmax)

Timepoint

At 0 (before dosing), 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 12, 24, 36 and 48 hour after dosing

Method of measurement

High-performance liquid chromatography—mass spectrometry (HPLC-MS-MS)

Secondary outcomes

1

Description

AUC (Area Under the Concentration-Time Curve)

Timepoint

At 0 (before dosing), 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 12, 24, 36 and 48 hour after dosing.

Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA) or SPSS

Intervention groups

1

Description

Intervention group 1: In this group, volunteers are given a single oral dose of Empagliflozin tablet 10 mg produced by Zist Arvand Pharmed Co. (Domestic). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 2.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, volunteers are given a single oral dose of Empagliflozin tablet 10 mg (Jardiance®), produced by Boehringer Ingelheim Company (Brand). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 1.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Drug Applied Research Center

Full name of responsible person

Hamed Hamishehkar

Street address

Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshgah Blvd, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165665811

Phone

+98 41 3336 7914

Fax

+98 41 3336 7914

Email

Hamishehkar.hamed@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zist Arvand Pharmed Pharmaceutical Company

Full name of responsible person

Mohammad Kazem Khoeeniha

Street address

Siraj Complex, Pardis Technology Park, Km 20 Damavand Road, Tehran

City

Tehran

Province

Tehran

Postal code

1657163871

Phone

+98 21 7625 0250

Fax

+98 21 7625 0100

Email

info@techpark.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zist Arvand Pharmed 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

Hamed Hamishehkar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutics

Street address

Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshgah Blvd, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165665811

Phone

+98 41 3336 7914

Email

Hamishehkar.hamed@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Jaber Emami

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutics

Street address

Hezarjarib St., School of Pharmacy and Pharmaceutical Sciences , Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7111

Fax

+98 31 3668 0011

Email

Emami@pharm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Fatima Molavi

Position

Non-Faculty Academic Position

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutics

Street address

Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshgah Blvd, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165665811

Phone

+98 41 3336 7914

Email

F.molavi85@gmail.com

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

There is no further information

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

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

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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