Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparative bioequivalence study of the Empagliflozin 25-mg Tablets manufactured by Rayhaneh Pharmaceutical Company

Protocol summary

Study aim

Demonstration of bioequivalence of Empagliflozin tablet 25 mg of Rayhaneh Co. with Jardiance® tablet manufactured by Boehringer Ingelheim after single dose administration.

Design

Single dose, randomized and crossover bioequivalence study of Empagliflozin tablet 25 mg by Rayhaneh Co. with Jardiance® (Boehringer Ingelheim) in 24 healthy 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 volunteers will receive one of the 25 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 subjects in the age range of 18-60 years and BMI (Body Mass Index) of 18-30. Exclusion criteria: Subjects with Blood Pressure ≤ 90/60 mm/Hg or BP ≥ 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

ntervention group 1: Empagliflozin tablet 25 mg by Rayhaneh 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: **IRCT20130313012810N17**
Registration date: **2023-11-08, 1402/08/17**
Registration timing: **prospective**

Last update: **2023-11-08, 1402/08/17**
Update count: **0**

Registration date

2023-11-08, 1402/08/17

Registrant information

Name

Hamed Hamishehkar

Name of organization / entity

Drug Applied Research Center, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 3311

Email address

hamishehkar.hamed@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-16, 1402/08/25

Expected recruitment end date

2023-11-28, 1402/09/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of the Empagliflozin 25-mg Tablets manufactured by Rayhaneh Pharmaceutical Company

Public title

Comparative bioequivalence study of the Empagliflozin 25-mg Tablets manufactured by Rayhaneh Pharmaceutical Company

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

The weight range of participating candidates should be between 60-100 kg Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw

Exclusion criteria:

History of allergic or adverse reaction to Azithromycin or any similar product Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg Smokers Individuals who donated whole blood or blood components within 2 months within 2 weeks prior to the first dose of the study product(s)

Age

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

Gender

Both

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 Sciences

Street address

Daneshghah St. Drug Applied Research Center

City

Tabriz

Province

East Azarbaijan

Postal code

5165665811

Approval date

2023-10-16, 1402/07/24

Ethics committee reference number

IR.TBZMED.REC.1402.549

Health conditions studied

1

Description of health condition studied

Bioequivalence study in healthy volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma concentration of the drug

Timepoint

15 sampling time included pre-dose (time 0) and at the following hours post-dose: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 12, 24, and 48 h

Method of measurement

Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, volunteers are given a single oral dose of Empagliflozin tablet 25 mg produced by Rayhaneh 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
N/A

2

Description
Intervention group 2: In this group, volunteers are given a single oral dose of Empagliflozin tablet 25 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
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Drug Applied Research Center, Tabriz University of Medical Sciences
Full name of responsible person
Hamed Hamishehkar
Street address
Drug Applied Research Center, Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
51656-65811
Phone
+98 41 3336 3311
Email
hamishehkar.hamed@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rayhaneh Pharmaceutical Company
Full name of responsible person
Yahya hazaei
Street address
2nd floor, No. 5., Parvaneh St.,Jalal Al Ahmad,Tehran St
City
Tehran
Province
East Azarbaijan
Postal code
1439915481
Phone
+98 21 5765 5000
Email
info@rayhanehpharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rayhaneh 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
Medical Pharmacy
Street address
Drug Applied Research Center, Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
51656-65811
Phone
+98 41 3336 3181
Fax
+98 41 3336 3311
Email
hamishehkar.hamed@gmail.com
Web page address
http://darc.tbzmed.ac.ir/

Person responsible for scientific 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
Medical Pharmacy

Street address
Drug Applied Research Center, Tabriz University of Medical Sciences

City
Tabriz

Province
East Azarbaijan

Postal code
51656-65811

Phone
+98 41 3336 3181

Fax
+98 41 3336 3311

Email
hamishehkar.hamed@gmail.com

Web page address
http://darc.tbzmed.ac.ir/

Person responsible for updating data

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
Medical Pharmacy

Street address
Drug Applied Research Center, Tabriz University of Medical Sciences

City
Tabriz

Province
East Azarbaijan

Postal code
51656-65811

Phone
+98 41 3336 3181

Fax
+98 41 3336 3311

Email
hamishehkar.hamed@gmail.com

Web page address
http://darc.tbzmed.ac.ir/

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
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