

# 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  $\leq$  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 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 (C<sub>max</sub>); 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

Daneshgah 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 hazaie

##### 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

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##### Web page address

http://darc.tbzmed.ac.ir/

## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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**Position**

professor

**Latest degree**

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## Person responsible for updating data

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**Position**

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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**

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