

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative bioequivalence study of the Empagliflozin 25-mg tablets manufactured by DarmanYab Darou Pharmaceutical Company with Empagliflozin brand tablets (Jardiance®) by Boehringer Ingelheim.

#### Protocol summary

##### Study aim

Demonstration of bioequivalence of Empagliflozin tablet 25 mg of DarmanYab Darou 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 DarmanYab Darou 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 of the two 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 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 25 mg by DarmanYab Darou 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: **IRCT20200407046981N36**

Registration date: **2022-07-26, 1401/05/04**

Registration timing: **prospective**

Last update: **2022-07-26, 1401/05/04**

Update count: **0**

##### Registration date

2022-07-26, 1401/05/04

##### 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

2022-12-20, 1401/09/29

##### Expected recruitment end date

2023-01-19, 1401/10/29

**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 DarmanYab Darou Pharmaceutical Company with Empagliflozin brand tablets (Jardiance®) by Boehringer Ingelheim.

**Public title**

Study of absorption and elimination rate of Empagliflozin tablets 25 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  $\leq$  90/60 mm/Hg or BP  $\geq$  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**

2022-07-10, 1401/04/19

**Ethics committee reference number**

IR.TBZMED.REC.1401.329

**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 25 mg produced by Darman Yab Darou 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 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

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

Darmanyab darou pharmaceutical company

#### Full name of responsible person

Parisa Mansouri

#### Street address

No. 36, 20th St, kordestan high way, Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

1437634561

#### Phone

+98 21 87174

#### Fax

+98 21 8714 5120

#### Email

info@darmanyab.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Darmanyab darou 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

Fatima Molavi

##### Position

Non-Faculty Academic Position

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Pharmaceutics

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

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##### Email

Molavif@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**

Pharmaceutics

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## 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.

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## 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