Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 ≤ 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

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 (Cmax); 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)

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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 ≤ 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
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

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

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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

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Email
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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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Position
Professor

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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