Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative bioequivalence study of Empagliflozin/Metformin 12.5/1000 mg Combined Tablet of Darman Yab Darou Pharmaceutical Co. and Synjardy of Boehringer Ingelheim

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Empagliflozin/Metformin 12.5/1000 mg Tablet formulation as a test product with Synjardy Tablet of Boehringer Ingelheim formulation as a reference product and to evaluate the bioequivalence of these two formulations.

Design

Non-blinded, randomized, crossover in vivo bioequivalence study in 24 healthy Volunteer under fasting conditions. Block randomization for a treatment sequence of Test/Reference or Reference/Test is used.

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Noor Research and Development Institute (Tarasht, Tehran). 2 dosing periods will be separated by a 7-day washout period.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthy subjects (male) between 18–55 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Exclusion Criteria: Subjects with known allergy to the products tested. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period.

Intervention groups

ntervention group 1: Empagliflozin/Metformin 12.5/1000 mg Tablet, produced by Darman Yab Darou Pharmaceutical Co. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: Jardiance 10 mg Tablet, produced by Boehringer Ingelheim is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N99**
Registration date: **2025-11-22, 1404/09/01**
Registration timing: **prospective**

Last update: **2025-11-22, 1404/09/01**
Update count: **0**

Registration date

2025-11-22, 1404/09/01

Registrant information

Name

Behzad Montaha Sangari

Name of organization / entity

Noor research and educational institute (Tavan)

Country

Iran (Islamic Republic of)

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+98 21 6600 7026

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-26, 1404/10/05

Expected recruitment end date

2026-01-02, 1404/10/12

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of Empagliflozin/Metformin 12.5/1000 mg Combined Tablet of Darman Yab Darou Pharmaceutical Co. and Synjardy of Boehringer Ingelheim

Public title
Comparative in vivo evaluation of 2 formulations of Empagliflozin/Metformin 12.5/1000 mg Tablet
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy subjects (male) between 18– 55 years of age. Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects with normal vital signs Subjects who agree with patient consent form.
Exclusion criteria:
Subjects with known allergy to the products tested. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period Subjects who has used any prescription or OTC drugs 14 days prior to the initiation of study and unable to refrain from the concomitant medications. History of alcohol or drug abuse. Heavy drinker of caffeine, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity. A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study.
Age
From **18 years** old to **55 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
The randomization schedule will be generated with https://www.sealedenvelope.com/simple-randomiser/v1/lists. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer numbers (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of Test/Reference or Reference/Test will be given to each volunteer.
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 Shahid Beheshti University of Medical Sciences
Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1996835113
Approval date
2025-10-20, 1404/07/28
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1404.176

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus without complications
ICD-10 code
E11.9
ICD-10 code description
Type 2 diabetes mellitus without complications

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)
Timepoint
0, 0/5، 1، 1/5، 2، 2/5، 3، 3/5، 4، 6، 8، 11، 24 and 48 hours after administration
Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)
Timepoint
0، 0/5، 1، 1/5، 2، 2/5، 3، 3/5، 4، 6، 8، 11، 24 and 48 hours after administration
Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Intervention groups

1

Description
Intervention group 1: Empagliflozin/Metformin 12.5/1000 mg Tablet , produced by Darman Yab Darou Co. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Noor Research & Development Institute (Tavan)
Full name of responsible person
Behzad Montaha Sangari
Street address
Sharif Innovation Station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.
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info@tavaninstitute.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Darman Yab Darou pharmaceutical Co.
Full name of responsible person
Mohammad Bashari
Street address
Tehran - Kurdistan Highway - 20th Street - Corner of Azadegan Blvd. - No. 36
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Postal code
1437634561
Phone
+98 21 8717 5000
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
Darman Yab Darou pharmaceutical Co.
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
Noor research and educational institute (Tavan)
Full name of responsible person
Behzad Montaha Sangari
Position
CEO
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

Contact
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Noor research and educational institute (Tavan)
Full name of responsible person

Seyed Mohsen Foroutan
Position
Principal investigator
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact
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Full name of responsible person
Behzad Montaha Sangari
Position
CEO
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
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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
It's undetermind yet.
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