Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The bioequivalence study of empagliflozin 10 mg tablets of Daram Yab Darou pharmaceutical company compared to the sample of empagliflozin 10 mg manufactured by Boehringer Ingelheim and Eli Lilly, Germany, on healthy volunteers.

Protocol summary

Study aim
Comparison of the absorption of two formulations of the same drug (Empegliflozin oral tablet 10 mg).

Design
Bioequivalence studies (bioequivalence) of empagliflozin 10 mg tablets produced by Yayab Pharmaceuticals compared to empagliflozin 10 mg manufactured by Boehringer Ingelheim and Eli Lilly, Germany, including in vivo tests after administration to 24 healthy human volunteers with ethical approval And it is covered by liability insurance.

Settings and conduct
On-site study: Nik Azma Pars Alborz Company Address of the laboratory: Alborz Province, Mahdasht, Imam Khomeini Blvd., Azadegan Sqr, No. 419, Unit 3, Postal Code 3188913179 The study consists of two phases (taking one empegliflozin 10 mg tablet orally at each study time, for a total of 2 times) with a one-week washout period (when the drug is completely out of your blood). Each stage lasts 48 hours, the total participation time of volunteers in both stages of this study will be a total of 96 hours. In the first stage of the study, you will be randomly assigned to one of the following two groups: group one consumes formula A and group two consumes formula B. Formulas A and B are products in the form of tablets produced in Germany and Iran.

Participants/Inclusion and exclusion criteria
A: Entry criteria: - . Be between 18 and 50 years old. - all Candidates must be non-smokers. - Body mass index (BMI) The candidate must be less than 30 kg for the square of their height in meters. B: Non-entry criteria: - Volunteers with blood pressure less than 90.60 mmHg or higher 90/140 mm Hg. - The candidate should stop smoking, drinking Alcohol, caffeine (including coffee, cocoa, tea, cola drinks) from 48 Avoid hours before starting to study.

Intervention groups
The healthy, non-smoker volunteers with the age of 18 to 50 years. The study was started fasting and cross-over with time washing will be a week.

Main outcome variables
Drug plasma content

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230222057495N3**
Registration date: **2023-04-03, 1402/01/14**
Registration timing: **prospective**

Last update: **2023-04-03, 1402/01/14**
Update count: **0**

Registration date
2023-04-03, 1402/01/14

Registrant information

Name
Monireh Jalalipour

Name of organization / entity
Nikazma Pars Alborz company

Country
Iran (Islamic Republic of)

Phone
+98 26 3731 8748

Email address
info@naplab.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15
Expected recruitment end date
2023-09-06, 1402/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The bioequivalence study of empagliflozin 10 mg tablets of Daram Yab Darou pharmaceutical company compared to the sample of empagliflozin 10 mg manufactured by Boehringer Ingelheim and Eli Lilly, Germany, on healthy volunteers.

Public title
Bioequivalence study of empagliflozin 10 mg tablet
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Be between 18 and 50 years old. All candidates must be non-smokers. The Volunteer's body mass index (BMI) should be less than 30 kg for the square of their height in meters.
Exclusion criteria:
Volunteers with blood pressure less than 90/60 mm Hg or higher than 140/90 mm Hg. Volunteers should refrain from smoking, consuming alcohol, caffeine (including coffee, cocoa, tea, cola drinks) 48 hours before the start of the study.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **30**
In each sample, 5 cc of blood is taken from the participant at 15 time intervals. And this process is repeated twice (totally 30 samples from each person).
Randomization (investigator's opinion)
Not randomized
Randomization description
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 Tehran University of Medical Sciences
Street address
Institute of Pharmaceutical Sciences, Faculty of Pharmacy, Tehran University of Medical Sciences, Porsina Street
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2023-03-07, 1401/12/16
Ethics committee reference number
IR.TUMS.TIPS.REC.1401.136

Health conditions studied

1

Description of health condition studied
In the present study, no disease was investigated.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Empagliflozin plasma concentrations
Timepoint
0, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 12, 24, 36 and 48 hours
Method of measurement
HPLC-MS/MS

Secondary outcomes

empty

Intervention groups

1

Description
The study consists of two phases (taking one empegliflozin 10 mg tablet orally at each study time, for a total of 2 times) with a one-week washout period (when the drug is completely out of your blood). Each phase lasts 48 hours. You must fast for 10 hours before the start of each phase. On the morning of the study, you

must be present at the place of the study at 7:00 a.m. to have an angiocat installed on your arm and for 12 hours. It will remain on your hand. In order to continue sampling, without the need for the volunteer's permanent presence, and by referring to the mentioned time intervals, it is done by syringe. 5 ml of blood before drug administration and at sampling times based on hours, 15 time points including: 0, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 12, 24, 36 And 48 will be taken from you (15 times in total). To prevent hypoglycemia, the drug is prescribed with 240 ml of glucose 20 solution in water, and then 60 ml of glucose solution every 15 minutes to 4 hours after the dose. With a gap of one week after receiving the first drug, the candidates must go to receive another drug and all these steps will be repeated. The total duration of participation of the candidates in both stages of this study will be a total of 96 hours, the candidates will be covered by Pasargad insurance for the entire duration of this study, and all stages of this study will be commissioned and sponsored by Darman Yab Darou pharmaceutical company (as the employer in this study) are In the first stage of the study, you will be randomly assigned to one of the following two groups: group one formula A (Jardiance® brand produced by the foreign company Boehringer Ingelheim and Eli Lilly, Germany) and group two formula B (generic Empagliflozin by the domestic company Darman Pharmaceutical Company the drug tracer has been produced) consumes Formulas A and B are products in the form of 10 mg tablets.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Nik Azma Pars Alborz laboratory

Full name of responsible person
Monireh Jalalipour

Street address
No. 4, Imam Khomeini Boulevard, Azadegan Square

City
Mahdasht Karaj

Province
Alborz

Postal code
3188913179

Phone
+98 26 3731 8748

Email
info@naplab.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yab Daro Company

Full name of responsible person
Parisa Mansouri

Street address
No. 36, corner of Azadegan Boulevard, 20th (Abtahi) Street, Kurdistan Highway

City
Tehran

Province
Tehran

Postal code
1437634561

Phone
+98 21 87174

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
Yab Daro 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
Nik Azma Pars Alborz laboratory

Full name of responsible person
Monireh Jalalipour

Position
Responsible Pharmacist

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
No. 4, Imam Khomeini Boulevard, Azadegan Square

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Nik Azma Pars Alborz laboratory

Full name of responsible person
Monireh Jalalipour

Position
Responsible Pharmacist

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

Contact

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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
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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available