

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 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 (Empagliflozin 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 empagliflozin 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.

AgeFrom **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

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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