

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Bioequivalence study of empagliflozin 12.5 combined tablet with metformin 1000 mg of Daro Darman Pars company in comparison with the reference sample of Syngardi made by Boehringer company.

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and in vivo parameters of Empagliflozin 12.5+ Metformin 1000 mg Tablet formulation as a test product with Synjardy 12.5+ 1000 mg Tablet 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 males 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 20 – 45 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. Exclusion criteria: Subjects with known allergy to the products tested. History of diabetes or other endocrine diseases.

Intervention groups

Intervention group 1: Empagliflozin 12.5+ Metformin 1000 mg Tablet, produced by Darou Darman Pars. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: Synjardy 12.5+ 1000 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: **IRCT20180620040164N52**

Registration date: **2023-11-22, 1402/09/01**

Registration timing: **prospective**

Last update: **2023-11-22, 1402/09/01**

Update count: **0**

Registration date

2023-11-22, 1402/09/01

Registrant information

Name

Behzad Montaha Sangari

Name of organization / entity

Noor research and educational institute (Tavan)

Country

Iran (Islamic Republic of)

Phone

+98 21 6600 7026

Email address

info@tavaninstitute.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2023-12-20, 1402/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of empagliflozin 12.5 combined tablet with metformin 1000 mg of Daro Darman Pars company in comparison with the reference sample of Syngardi made by Boehringer company.

Public title

Comparative in vivo evaluation of 2 Empagliflozin 12.5 Combined Tablet with Metformin 1000 mg Tablet formulations.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy subjects (male) between 20 – 45 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. Subjects with normal vital signs. Subjects who agree with patient consent form.

Exclusion criteria:

Subjects with known allergy to the products tested. History of diabetes or other endocrine diseases making more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. 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 **20 years** old to **45 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/lits>. 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, School of Pharmacy, Nursing & Midwifery - Shahid Beheshti University of medical sciences

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2023-11-13, 1402/08/22

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.169

Health conditions studied

1

Description of health condition studied

Diabetes mellitus

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Peak Plasma Concentration (C_{max})

Timepoint

20 blood samples will be withdrawn pre-dose and at 0.33, 0.67, 1, 1.33, 1.67, 2, 2.33, 2.67, 3, 3.33, 3.67, 4, 4.5, 5, 6, 8, 12, 24 and 48 hours after intervention.

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

20 blood samples will be withdrawn pre-dose and at 0.33, 0.67, 1, 1.33, 1.67, 2, 2.33, 2.67, 3, 3.33, 3.67, 4, 4.5, 5, 6, 8, 12, 24 and 48 hours after intervention.

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 12.5+ Metformin 1000 mg Tablet , produced by Darou Darman Pars. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 07-day wash-out period the intervention 2 will be given to these subjects.

Category

Treatment - Drugs

2

Description

Intervention group 2: Empagliflozin 12.5+ Metformin 1000 mg Tablet (Synjerd®), produced by Boehringer Ingelheim is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 07-day wash-out period the intervention 1 will be given to these subjects.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor Research & Development Institute (Tavan)

Full name of responsible person

Ali Aghaei

Street address

Sharif Innovation Station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.

City

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1459926609

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Email

info@tavaninstitute.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Darou darman Pars Co.

Full name of responsible person

Mohsen Hashemi

Street address

No 27, West Emdad St., North Sheekh Bahaei St., Tehran

City

Tehran

Province

Tehran

Postal code

1459926609

Phone

+98 21 8861 0479

Email

info@ddp-group.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Darou darman Pars 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 & Development Institute

Full name of responsible person

Ali Aghaei

Position

Master

Latest degree

Master

Other areas of specialty/work

Pharmacy

Street address

Sharif innovation station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tavan Institute

Full name of responsible person

Seyed Mohsen Foroutan

Position

Principal investigator

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Position

Master

Latest degree

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Pharmacy

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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

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