Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

In- Vivo Bioequivalence study of Empagliflozin-Metformin tablet (EMPATUS Plus® 25/1000 mg ,Pars Darou Pharma, Iran) with brand drug (Synjardy® 25/1000 mg, Boehringer Ingelheim, Germany) in Iranian healthy

Protocol summary

Study aim

In- Vivo Bioequivalence study of Empagliflozin-Metformin tablet (EMPATUS Plus® 25/1000 mg ,Pars Darou Pharma, Iran) with brand drug (Synjardy® 25/1000 mg, Boehringer Ingelheim, Germany) in Iranian healthy

Design

In-vivo bioequivalence study of EMPATUS Plus tablet Pars Darou Pharma. in compared with reference drug (Synjardy, Boehringer Ingelheim, German). The study design is single blind, Cross-over, two period & two groups (Intervention and control) with one week wash-out time. Randomization of the drug types in each period will perform by paper lottery randomization.

Settings and conduct

Study background is biopharmacy and pharmcokinetics. Place of study is Simin Baspar Tayf-Gostar Inc, Tabriz. Study blinding will done by taking the test and reference drugs out of their original packaging and put them in the similar packaging. The volunteers will not be informed about the type of received drug. In cross-over design, the test drug will taken by group 1 in first period and by group 2 in second period. The reference drug also will taken by group 2 in the first period and by group 1 in the second period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-55 years, body mass index (BMI) in the range of 18-28. Exclusion criteria: History of heart, kidney and liver disease, Pregnancy, Drug addiction, Smoking

Intervention groups

Single dose EMPATUS Plus tablet Pars Darou Pharma. Control group: brand drugs (Synjardy, Boehringer Ingelheim, German)

Main outcome variables

Plasma drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N60**
Registration date: **2022-05-05, 1401/02/15**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-05, 1401/02/15**
Update count: **0**

Registration date

2022-05-05, 1401/02/15

Registrant information

Name

Javad Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3661 4125

Email address

shokri.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-09, 1400/12/18

Expected recruitment end date

2022-09-09, 1401/06/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
In- Vivo Bioequivalence study of Empagliflozin-Metformin tablet (EMPATUS Plus® 25/1000 mg ,Pars Darou Pharma, Iran) with brand drug (Synjardy® 25/1000 mg, Boehringer Ingelheim, Germany) in Iranian healthy

Public title
In-vivo Bioequivalence Test of Empagliflozin-Metformin tablets with brand drug (Synjardy® 25/1000 mg, Boehringer Ingelheim, Germany)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
General health Body mass index between18-28 Informed consent Being at the age of 18-55 years old

Exclusion criteria:
Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
For this purpose, A 24- persons group will be selected and divided to two 12-persons groups randomly. The names of all volunteers will be written on paper pieces and wrapped in aluminum foils. The first 12 papers will randomly be withdrawn from bottle will be selected as group A and others will be categorized in group B.

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 Sciences

Street address
Third floor; Central building; Tabriz University of Medical Sciences; Dneshgah St.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2021-11-29, 1400/09/08

Ethics committee reference number
IR.TBZMED.REC.1400.825

Health conditions studied

1

Description of health condition studied
Bio equivalence test

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Plasma drug concentration

Timepoint
Sampling times in this study will be 0, 0:30, 1, 1:30, 2, 2:30, 3, 4, 6, 8, 10, 12, 24, 48 hours after prescribing the tablet.

Method of measurement
High performance liquid chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One test tablet (EMPATUS Plus® 25/1000 mg ,Pars Darou Pharma, Iran) will be received. Blood samples will be taken for 72 hours at the mentioned times after drug administration and the concentration of the drug in Plasma samples will be measured by liquid chromatography with mass spectroscopy detector

Category
Treatment - Other

2

Description
Control group: One Reference tablet (Synjardy® 25/1000 mg, Boehringer Ingelheim, German) will be received. Blood samples will be taken for 72 hours at the

mentioned times after drug administration and the concentration of drag in plasma samples will be measured by liquid chromatography with mass spectroscopy detector.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Simin Baspar Teyf Gostar Company

Full name of responsible person

Javad Shokri

Street address

No.48, Ferdos square

City

Tabriz

Province

East Azarbaijan

Postal code

5167874434

Phone

+98 41 3384 2724

Email

Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pars Darou Pharmaceutical Company

Full name of responsible person

Amir Garmabadri

Street address

Tehran, the first square of Tehranpars, in front of 144 East Street, No.13

City

Tehran

Province

Tehran

Postal code

1654713691

Phone

+98 21 7770 4061

Email

info@parsdarou.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pars 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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Javad Shokri

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Faculty of Pharmacy, Tabriz University of Medical Sciences, Daneshgah

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Javad Shokri

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dariush.omidfar

Position
Lab. Manager

Latest degree
Master

Other areas of specialty/work
Others

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Tabriz

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Phone
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Email
Dariush.omidfar@gmail.com

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
All information and data of the study will remain secured based on the agreement established between researcher and drug producer.

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
Yes - There is a plan to make this available

Title and more details about the data/document
Only protocol and methods of study are sharable

When the data will become available and for how long
The access to data will be possible after finishing of project (almost 6 months after receiving of IRCT Code).

To whom data/document is available
Pharmaceutical and medical sciences researchers

Under which criteria data/document could be used
Projects information's for any publications is not allowed.

From where data/document is obtainable
By email to the project manager (shokri.j@gmail.com)

What processes are involved for a request to access data/document
These information are confidential and be under disposal of the project's contractor. Upon request, the information will be accessed to the applicant by the Executor's email after receiving contractor's consent.

Comments