

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

In- Vivo Bioequivalence study of Metformin ER tablets1000 mg Kooshan Pharmed Co. (Gly-Once® 1000 mg ER Tablet) with brand drugs (Glucophage® 1000 mg ER Tablet ,Merck Sharp & Dohme, Germany) in Iranian healthy volunteers.

Protocol summary

Study aim

In- Vivo Bioequivalence study of Metformin ER tablets1000 mg Kooshan Pharmed Co. (Gly-Once® 1000 mg ER Tablet) with brand drugs (Glucophage® 1000 mg ER Tablet ,Merck Sharp & Dohme, Germany) in Iranian healthy volunteers.

Design

In-vivo bioequivalence study of Metformin ER tablets1000 mg Kooshan Pharmed Pharma in comparison with reference drug (Glucophage® 1000 mg ER Tablet ,Merck Sharp & Dohme, Germany).The single blind, Cross-over, two period, two groups (Intervention and control) and randomized (paper lottery randomization method) study with one week wash-out time.

Settings and conduct

This study is carried out in Simin Baspar Tayf-Gostar Company, Tabriz, Iran. The study population is 24 healthy Iranian volunteers.This study is a single blind study and by taking out the drugs from the existing packaging, the volunteers will not know the time of receiving the test drug and the brand. This study is a cross over study that is performed in two time periods of 24 hours with a two-week wash-out period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18-55 years old; body mass index (BMI) in the range of 18-28. Exclusion criteria: history of heart, kidney and liver disease; pregnancy; drug addiction.

Intervention groups

Single dose Metformin ER tablets1000 mg Kooshan Pharmed Pharma. Control group: Single dose Glucophage® 1000 mg ER Tablet ,Merck Sharp & Dohme, Germany

Main outcome variables

Plasma drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N70**

Registration date: **2022-10-20, 1401/07/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-20, 1401/07/28**

Update count: **0**

Registration date

2022-10-20, 1401/07/28

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

2022-10-17, 1401/07/25

Expected recruitment end date

2023-06-15, 1402/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In- Vivo Bioequivalence study of Metformin ER tablets1000 mg Kooshan Pharmed Co. (Gly-Once® 1000 mg ER Tablet) with brand drugs (Glucophage® 1000 mg ER Tablet ,Merck Sharp & Dohme, Germany) in Iranian healthy volunteers.

Public title

In-vivo Bioequivalence Test of Metformin ER tablets1000 mg Kooshan Pharmed with brand drug (Glucophage® 1000 mg ER Tablet ,Merck Sharp & Dohme, German)

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 dru

Age

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

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Care provider

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)

Single blinded

Blinding description

Candidates are not aware of receiving the test drug or brand one. In a single study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Test and Brand drugs are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test drug.

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

2022-10-10, 1401/07/18

Ethics committee reference number

IR.TBZMED.REC.1401.616

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, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 10 ,8, 12 , 24 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 (Metformin ER tablets1000 mg Kooshan Pharmed) will be received. Blood samples will be taken for 24 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 Glucophage® 1000 mg ER Tablet ,Merck Sharp & Dohme, Germany will be received. Blood samples will be taken for 24 hours at the mentioned times after drug administration and the concentration of drug 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

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No.48, Ferdos square

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Shokri.j@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Koushan Pharmed Pharmaceutical Company

Full name of responsible person

Delaram Amini

Street address

No.15, Padidar Alley, Africa Blvd

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Province

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Phone

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Email

CRM@koushanpharmed.com

Web page address

<http://www.koushanpharmed.com>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Koushan Pharmed 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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Simin Baspar Teyf Gostar Company

Full name of responsible person

Dariush Omidfar

Position

Lab. Manager

Latest degree

Master

Other areas of specialty/work

Bioanalysis

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Person responsible for updating data**Contact****Name of organization / entity**

Simin Baspar Teyf Gostar Company

Full name of responsible person

Ahad Sheikhloo

Position

Official Manager

Latest degree

Master

Other areas of specialty/work

Biochemistry

Street address

No.48, Ferdos square

City

Tabriz

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

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