

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### In- Vivo Bioequivalence study of Metformin 500mg tablets (Zagross Darou Pharma) with brand drug (Glucophage® 500mg, Merck Serono, Germany) in Iranian healthy volunteers.

#### Protocol summary

##### Study aim

In- Vivo Bioequivalence study of Metformin 500mg tablets (Zagross Darou Pharma) with brand drug (Glucophage® 500mg, Merck Serono, Germany) in Iranian healthy volunteers.

##### Design

Single dose, randomized, two sequences, two period crossover with a washout period.

##### Settings and conduct

This study will be conducted in one-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of 72 hours. The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form. In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives a similar tablet. Blood samples will be taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them.

##### Participants/Inclusion and exclusion criteria

24 participants will be selected from non-smoking, not pregnant people with no history of heart, kidney and liver disease or dis function, both sex (male&female). The ages and BMIs of participant should be in the range of 18-60 and 18-28 respectively.

##### Intervention groups

Intervention group Single dose Metformin 500mg Zagross Darou Pharmaceutical Company with brand drugs (Glucophage® 500mg, Merck Serono, Germany)

##### Main outcome variables

Determination of blood drug concentration.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200105046010N36**

Registration date: **2021-08-06, 1400/05/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-08-06, 1400/05/15**

Update count: **0**

##### Registration date

2021-08-06, 1400/05/15

##### 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

2021-04-19, 1400/01/30

##### Expected recruitment end date

2021-12-21, 1400/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

In- Vivo Bioequivalence study of Metformin 500mg tablets (Zagross Darou Pharma) with brand drug (Glucophage® 500mg, Merck Serono, Germany) in Iranian healthy volunteers.

## Public title

In-vivo Bioequivalence Test of Metformin 500mg tablet (Zagross Darou Pharma)

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

General health Body mass index(18-28) Informed consent Age(18-60)

### 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 **60 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, first determine a total sample size (24 people), then write the names of the people on paper, and after folding in aluminum foil, pour it into a glass, and then randomly remove the papers and open the first 12 people in group A and The rest are selected as 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, Tabriz University of Medical Sciences

## Street address

Third floor of TUMS (Tabriz University of Medical Sciences) central building, Dneshgah St. Tabriz, Iran

## City

Tabriz

## Province

East Azarbaijan

## Postal code

5166614766

## Approval date

2021-03-01, 1399/12/11

## Ethics committee reference number

IR.TBZMED.REC.1399.1155

## Health conditions studied

### 1

#### Description of health condition studied

In this study, the disease is not examined. Subject bioequivalence test and reference tablets Metformin studied.

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Determination of blood drug concentration.

#### Timepoint

Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 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: Intervention group received one test drug table(Metformin tablet 500 mg Zagross Darou Pharma ).

#### Category

Treatment - Other

### 2

#### Description

Control group: Control group received one reference drug table(Metformin tablet 500 mg GLUCOPHAGE® Merck Serono, Germany).

#### 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 Street

**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**

Zagross Darou Pharmaceutical Company

**Full name of responsible person**

Asem Abollahpor

**Street address**

West Town - Farahzadi Boulevard - East 1st Park - No.  
37 - Zagros Building

**City**

Tehran

**Province**

Tehran

**Postal code**

1389776363

**Phone**

+98 21 4300 0070

**Email**

info@zagrosdarou.com

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

No

**Title of funding source**

Zagross 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**

Other

## 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

**Street address**

Faculty of Pharmacy, Tabriz University of Medical  
Sciences.

**City**

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**Postal code**

5166414766

**Phone**

+98 41 3334 8489

**Email**

Shokri.j@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Javad Shokri

**Position**

Professor

**Latest degree**

Ph.D.

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## Person responsible for updating data

#### Contact

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**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**

These data are as secure between researcher and related industries .

**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**

Only protocol and methods of study are sharable.

**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**

This information is confidential and is at the disposal of the project sponsor. Upon request, the information will be provided to the applicant by the contractor's email after the

**Comments**