

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### **Bioequivalence study of Metformin 500 mg ( VARIOMET® 500 mg) manufactured by Faran pharmed versus originator brand GLUCOPHAGE® 500 mg manufactured by Merck Serono Germany in healthy volunteers**

#### **Protocol summary**

##### **Study aim**

Bioequivalence study of Metformin 500 mg ( VARIOMET® 500 mg) manufactured by Faran Pharmed Co. versus originator brand GLUCOPHAGE® 500 mg manufactured by Merck Serono Germany in healthy volunteers.

##### **Design**

Bioequivalence study, crossover, single-blinded, 24 healthy volunteers. Simple randomization was used for randomization

##### **Settings and conduct**

The study is a single-blinded, cross-over and fasting, and on two series of healthy volunteers. The study will be done in two periods (24h). The interval between these two periods is a week. In the first round of the study, the candidates were divided into two groups the first group received a test tablet and the second group received a brand tablet. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. Sampling is performed in Radin laboratory in Tabriz.

##### **Participants/Inclusion and exclusion criteria**

Inclusion Criteria: General Health (Liver, Heart, and Kidney), Body Mass Index (18-28), Informed consent, Age (18-55 years old) Exclusion criteria: Smoking, History of cardiovascular disease, History of liver and kidney disease, Alcohol and drug addiction, History of allergy to Metformin

##### **Intervention groups**

Intervention group 1: GLUCOPHAGE® 500 mg tablet as a reference Intervention group 2: VARIOMET® 500 mg Tablet manufactured by Faran Pharmed as a test

##### **Main outcome variables**

Maximum drug concentration, Time to reach maximum drug concentration

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20200105046010N98**

Registration date: **2024-02-21, 1402/12/02**

Registration timing: **prospective**

Last update: **2024-02-21, 1402/12/02**

Update count: **0**

##### **Registration date**

2024-02-21, 1402/12/02

##### **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**

2024-04-20, 1403/02/01

##### **Expected recruitment end date**

2025-04-21, 1404/02/01

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

##### **Trial completion date**

empty

**Scientific title**

Bioequivalence study of Metformin 500 mg ( VARIOMET® 500 mg) manufactured by Faran pharmed versus originator brand GLUCOPHAGE® 500 mg manufactured by Merck Serono Germany in healthy volunteers

**Public title**

Bioequivalence study of Metformin 500 mg ( VARIOMET® 500 mg) manufactured by Faran pharmed

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

General Health (Liver, Heart, and Kidney) Body Mass Index (18-30) Informed consent Age (18-55 years old)

**Exclusion criteria:**

Smoking History of cardiovascular disease Informed consent Age (18-55 years old) History of allergy to Metformin

**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**

People in the mentioned age group are invited to participate through the advertisement. People are then checked for health and healthy volunteers are identified. People are randomly placed in one of the two study groups with the help of a random number table and receive the intervention related to the same group. The volunteers don't have any information about taking the test drug or brand drug

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study is a single-blinded clinical trial (volunteers). Test and Originator brand's medicine 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 dosage form.

**Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tabriz University of Medical Sciences ethics committee

**Street address**

No. 48, Ferdows street, Ferdowsi Sq.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5167874434

**Approval date**

2024-01-14, 1402/10/24

**Ethics committee reference number**

IR.TBZMED.REC.1402.791

**Health conditions studied****1****Description of health condition studied**

This study is performed on healthy volunteers and drug concentration in plasma is determined.

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Drug plasma concentration

**Timepoint**

0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10,12,24h after drug administration

**Method of measurement**

Liquid Chromatography Mass-Mass

**Secondary outcomes****1****Description**

Time to reach maximum plasma concentration

**Timepoint**

After intervention

**Method of measurement**

Time to reach the maximum drug concentration in plasma is recorded.

**2****Description**

Extent of absorption

**Timepoint**

After intervention

**Method of measurement**

Calculation of area under curve of concentration -time

## Intervention groups

### 1

#### Description

Intervention group: single dose, one oral tablet  
GLUCOPHAGE® 500 mg manufactured by Merck Serono  
Germany as a reference product

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Single dose, one oral Metformin 500  
mg ( VARIOMET® 500 mg) tablet manufactured by Faran  
Pharmed company as test product

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Radin Laboratory

##### Full name of responsible person

Javad Shokri

##### Street address

No.22, first floor, Azadi alley, Moalem st., Abureihan  
St

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5154995671

##### Phone

+98 914 313 5843

##### Fax

+98 41 3384 2724

##### Email

shokri.j@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Faran Pharmed company

##### Full name of responsible person

Parsa Sirat

##### Street address

unit 1, No.32, Nirue entezami st., Attar square, Vanak  
Square

##### City

Tehran

##### Province

Tehran

##### Postal code

1994767611

##### Phone

+98 21 5794 1000

##### Email

info@faranpharmed.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Faran Pharmed 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

No 4, 10th Ave. Boostan Street, Roshdieh, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5155935357

##### Phone

+98 41 3661 4125

##### Fax

##### 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

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Professor

##### Latest degree

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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 researchers 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**

No - There is not a plan to make this available