

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Bioequivalence study of metformin 1000 mg tablets of Jalinous pharmaceutical company in comparison with metformin 1000 mg of Actover pharmaceutical company of Iran on healthy volunteers

#### Protocol summary

##### Study aim

Bioequivalence study of metformin 1000 mg tablets of Jalinous pharmaceutical company in comparison with metformin 1000 mg of Actover pharmaceutical company of Iran on healthy volunteers

##### Design

The present clinical trial includes the bioequivalence study of metformin 1000 mg tablets of Jalinous Pharmaceutical Company of Iran in comparison with metformin 1000 mg of Actover Pharmaceutical Company of Iran, after administration to 24 healthy human volunteers, in two intervention groups, in a cross-over, blinded manner. It is not done and is not random.

##### Settings and conduct

The study is carried out at Nik Azma Pars Alborz company located in Mahdasht Karaj. The blinded cross-over study includes two stages (oral consumption of one 1000 mg metformin tablet per study and 2 times in total) with a one-week washout period on 24 fasting healthy volunteers. Then the obtained blood samples are determined.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy volunteers; Age between 18 and 55 years; non smoker; Exclusion criteria: candidates with blood pressure less than 90 on 60 mm Hg or higher than 140 on 90 mm Hg.

##### Intervention groups

The study includes two stages in the form of intervention 1: including the oral intake of 1000 mg metformin tablets from Iran's Jalinous Pharmaceutical Company and intervention 2: the intake of 1000 mg metformin tablets from Actover Pharmaceutical Company in Iran. This study will be repeated on fasting volunteers in a cross-sectional manner with an interval of one week.

##### Main outcome variables

Maximum plasma concentration of metformin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230222057495N14**

Registration date: **2024-02-27, 1402/12/08**

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

Last update: **2024-02-27, 1402/12/08**

Update count: **0**

##### Registration date

2024-02-27, 1402/12/08

##### Registrant information

##### Name

Monireh Jalalipour

##### Name of organization / entity

Nikazma Pars Alborz company

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3731 8748

##### Email address

info@naplab.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-20, 1402/12/01

##### Expected recruitment end date

2026-02-20, 1404/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Bioequivalence study of metformin 1000 mg tablets of Jalinous pharmaceutical company in comparison with metformin 1000 mg of Actover pharmaceutical company of Iran on healthy volunteers

### Public title

Bioequivalence study of metformin 1000 mg tablets

### Purpose

Other

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Healthy volunteer between 18 and 55 years old. Body mass index less than 30 kg per square meter. All candidates must be non-smokers.

#### Exclusion criteria:

Blood pressure less than 90 on 60 mm Hg or more than 140 on 90 mm Hg. Consumption of any drug, alcohol or tobacco within 2 weeks before receiving 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**

More than 1 sample in each individual

Number of samples in each individual: **32**

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### Randomization (investigator's opinion)

Not randomized

### Randomization description

### 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

Research Institute of Pharmaceutical Sciences,  
Tehran University of Medical Sciences

##### Street address

Institute of Pharmaceutical Sciences, Faculty of  
Pharmacy, Tehran University of Medical Sciences,  
Porsina Street

### City

Tehran

### Province

Tehran

### Postal code

1417613151

### Approval date

2024-02-17, 1402/11/28

### Ethics committee reference number

IR.TUMS.TIPS.REC.1402.170

## Health conditions studied

### 1

#### Description of health condition studied

In this research, no disease is studied.

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Maximum plasma concentration of metformin

#### Timepoint

before starting to take the drug and: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10 and 24 hours later from taking medicine

#### Method of measurement

Liquid chromatography - spectrophotometric detector

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: includes the oral intake of metformin tablets of 1000 mg from Jalinous Pharmaceutical Company in Iran on 24 fasting healthy volunteers. 5 ml of blood at time intervals before starting the medication and: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10 and 24 hours after taking the drug, it is taken from the volunteers. The cross-over study consists of two phases (oral administration of one 1000 mg metformin tablet per study and 2 times in total) with a one-week washout period (when the drug is completely removed from your blood). The plasma concentration of metformin is determined by liquid chromatography-spectrophotometry.

#### Category

Other

### 2

#### Description

Intervention group 2: includes the oral intake of

metformin tablets of 1000 mg of Actover Pharmaceutical Company of Iran on 24 healthy fasting volunteers. 5 ml of blood at time intervals before starting the medication and: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10 and 24 hours after taking the drug, it is taken from the volunteers. The cross-over study consists of two phases (oral administration of one 1000 mg metformin tablet per study and 2 times in total) with a one-week washout period (when the drug is completely removed from your blood). The plasma concentration of metformin is determined by liquid chromatography-spectrophotometry.

**Category**

Other

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Nik Azma Pars Alborz Laboratory

**Full name of responsible person**

Monireh Jalalipour

**Street address**

No. 419, Azadegan Square, Imam Khomeini Boulevard

**City**

Mahdasht Karaj

**Province**

Alborz

**Postal code**

3188913179

**Phone**

+98 26 3731 8748

**Email**

info@naplab.ir

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Jalinous Pharmaceutical Company

**Full name of responsible person**

Atieh Amirpour

**Street address**

No. 18, 23rd St., Kilometer 10 of Karaj special road

**City**

Tehran

**Province**

Tehran

**Postal code**

1399833611

**Phone**

+98 21 4454 3351

**Email**

info@jalinous.com

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

Yes

**Title of funding source**

Jalinous 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**

Industry

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Nik Azma Pars Alborz laboratory

**Full name of responsible person**

Monireh Jalalipour

**Position**

Responsible Pharmacist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

No. 419, Azadegan Square, Imam Khomeini Boulevard

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Nik Azma Pars Alborz laboratory

**Full name of responsible person**

Monireh Jalalipour

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Nik Azma Pars Alborz laboratory

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**Phone**

**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**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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