

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Pharmacokinetic assessments of of Sitagliptine/ Metformin 50/500 tablet (Dicemia) Kooshan Pharmed Co with brand drugs (JANUMET 50/500mg (Merck Sharp & Dohme, Germany) in Iranian healthy volunteers

#### Protocol summary

##### Study aim

n- Vivo Bioequivalence study of Sitagliptine/ Metformin tablet 50/500mg Koushan Pharmed Co. with brand drugs (JANUMET 50/500mg (Merck Sharp & Dohme, Germany) in Iranian healthy volunteers.

##### Design

Single dose Sitagliptine/ Metformin tablet 50/500mg Koushan Pharmed Pharmaceutical Company

##### Settings and conduct

This study will be conducted in two-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of twenty-four 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

##### Participants/Inclusion and exclusion criteria

24 participants will be selected from non-smoking, non-pregnant people without history of heart, kidney and liver disease from both sex (male & female). The ages and BMIs of participant should be in the range of 18-55 and 18-28 respectively.

##### Intervention groups

Single dose Sitagliptine/ Metformin tablet 50/500mg Koushan Pharmed Pharmaceutical Company and Single dose Sitagliptine/ Metformin tablet JANUMET 50/500mg (Merck Sharp & Dohme, Germany).

#### Main outcome variables

Determination of blood drug concentration.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200105046010N20**

Registration date: **2021-01-13, 1399/10/24**

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

Last update: **2021-01-13, 1399/10/24**

Update count: **0**

##### Registration date

2021-01-13, 1399/10/24

##### 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

2020-12-21, 1399/10/01

##### Expected recruitment end date

2021-06-22, 1400/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Pharmacokinetic assessments of of Sitagliptine/  
Metformin 50/500 tablet (Dicemia) Kooshan Pharmed Co  
with brand drugs (JANUMET 50/500mg (Merck Sharp &  
Dohme, Gremany) in Iranian healthy volunteers

**Public title**  
Study of Sitagliptine/ Metformin table In-Vivo  
Bioequivalence in healthy volunteers

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
General health (liver, heart, kidney) Body Mass Index  
(BMI) between 18-28 Informed consent Age between  
18-60 Both male and female

**Exclusion criteria:**  
Smoking Hypersensitivity to the drug Alcohol & Drug  
addiction Pregnancy

**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**  
Random allocation law is the simplest method of finite  
randomization. This method represents a large block for  
the entire sample size, This means that a balance in the  
number of people assigned to each group will be  
achieved at the end of the study. 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)**  
Single blinded

**Blinding description**  
It is necessary to apply the scientific method of blind  
testing in some fields, such as drug testing. Candidates  
are not aware of the test drug or brand name. In a one-  
blind 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. Dicemia and JANUMET are  
removed from their packaging by the executor and  
placed in similar and coded cans.

**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

2020-10-12, 1399/07/21

#### Ethics committee reference number

IR.TBZMED.REC.1399.731

## Health conditions studied

### 1

#### Description of health condition studied

In this study the bioequivalence of test and brand of  
Sitagliptine/ Metformin tablets 50/500mg will be evaluated.

#### 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.

#### Method of measurement

Liquid Chromatography with tandem mass spectroscopy  
detector

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: Single dose of  
Sitagliptine/ Metformin tablet 50/500mg Koushan  
Pharmed Company as a test product.

#### Category

Treatment - Drugs

2

### Description

Control group: Control group:Single dose of Sitagliptine/  
Metformin tablet with brand drugs (JANUMET 50/500mg  
(Merck Sharp & Dohme, Germany)

### Category

Treatment - Drugs

## 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

Koushan Pharmed Pharmaceutical Company

#### Full name of responsible person

Delaram Amini

#### Street address

No.15, Padidar Alley, Africa Blvd

#### City

Tehran

#### Province

Tehran

#### Postal code

1518943814

#### Phone

+98 21 8819 7148

#### Fax

+98 21 8819 7153

#### 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

#### Street address

Faculty of Pharmacy, University of Medical Sciences,  
Daneshgah Street,Tabriz East Azerbaijan

#### City

Tabriz

#### Province

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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

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

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Javad Shokri

**Position**

Professor

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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 sponsor agrees.

**Comments**