

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,
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Email

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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