Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim

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

Design

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

Main outcome variables

Determination of blood drug concentration.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N12**
Registration date: **2020-10-25, 1399/08/04**
Registration timing: **prospective**

Last update: **2020-10-25, 1399/08/04**
Update count: **0**

Registration date

2020-10-25, 1399/08/04

Registrant information

Name
Javad Shokri
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 41 3661 4125
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shokri.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-10, 1399/08/20

Expected recruitment end date

2021-09-11, 1400/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In- Vivo Bioequivalence study of Sitagliptine/ Metformin tablet 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

- Participant

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. Sitagliptine/ Metformin 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

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

2020-08-24, 1399/06/03

Ethics committee reference number

IR.TBZMED.REC.1399.579

Health conditions studied

1

Description of health condition studied

In this study the bioequivalence of test and brand of Linagliptin tablets 5mg will 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: Single dose of Sitagliptine/ Metformin tablet 50/500mg Razak Company as a test product.

Category

Treatment - Drugs

2

Description
Control group:Single dose of Sitagliptine/ Metformin tablet with brand drugs (JANUMET 50/500mg (Merck Sharp & Dohme, Gremany)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Simin Baspar Teyf Gostar Company
Full name of responsible person
Javad Shokri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Razak Pharma
Full name of responsible person
Roya Aria
Street address
Km 10,Lashgari Expy, Tehran-IRAN
City
Tehran
Province
Tehran
Postal code
1389736615
Phone
+98 21 4452 5413
Fax
+98 21 4452 5410
Email
info@razakpharma.com
Web page address
http://razak-labs.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Razak Pharma
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
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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 date 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

After finishing of the protocol (Probably 6 months receiving IRCT code)

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

Contact with E-mail of the main researcher.

What processes are involved for a request to access data/document

Personal and academic details and the aim of the request.

Comments