

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative bioequivalence study of the Sitagliptin 50 mg/ Metformin 1000 mg Tablets manufactured by Rayhaneh Pharmaceutical Company

Protocol summary

Study aim

Examining the bioequivalency of domestically produced Sitagliptin / Metformin tablet formulations with brand samples (Janumet®)

Design

A single-group, not blinded, not randomized, bioequivalence clinical trial on 24 healthy volunteers.

Settings and conduct

The number of 24 healthy men in the age range of 18-60 years and the Body Mass Index range of 18-30, who are voluntarily selected through public notification. One tablet is taken fasting and blood is taken at 17 times point. One week later, the process is repeated for the brand medicine

Participants/Inclusion and exclusion criteria

The weight range of participating candidates should be between 60-100 kg. All candidates must be non-smokers. Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose. Volunteers who have agreed to an informed consent form

Intervention groups

After taking a Sitagliptin 50 / Metformin 1000 mg tablet from domestic company, 3 milliliters of blood will be collected from the volunteer in 16 times intervals for 72 hours. Three weeks later, the process is repeated for a brand sample tablet. The drug concentration is measured in plasma

Main outcome variables

Studying the Drug pharmacokinetic parameters including measuring the plasma concentrations of drugs for brand and test products, determining the desired and

important pharmacokinetic parameters in bioequivalence studies, AUCs, Tmax, Cmax, T1/2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130313012810N14**

Registration date: **2023-09-21, 1402/06/30**

Registration timing: **prospective**

Last update: **2023-09-21, 1402/06/30**

Update count: **0**

Registration date

2023-09-21, 1402/06/30

Registrant information

Name

Hamed Hamishehkar

Name of organization / entity

Drug Applied Research Center, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 3311

Email address

hamishehkar.hamed@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-12, 1402/07/20

Expected recruitment end date

2023-10-17, 1402/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of the Sitagliptin 50 mg/ Metformin 1000 mg Tablets manufactured by Rayhaneh Pharmaceutical Company

Public title

Comparative bioequivalence study of the Sitagliptin 50 mg/ Metformin 1000 mg Tablets manufactured by Rayhaneh Pharmaceutical Company

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

The weight range of participating candidates should be between 60-100 kg Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw

Exclusion criteria:

History of allergic or adverse reaction to Sitagliptin / Metformin or any similar product Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg Smokers Individuals who donated whole blood or blood components within 2 months within 2 weeks prior to the first dose of the study product(s)

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)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Daneshghah St. Drug Applied Research Center

City

Tabriz

Province

East Azarbaijan

Postal code

5165665811

Approval date

2023-09-04, 1402/06/13

Ethics committee reference number

IR.TBZMED.REC.1402.431

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

-

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

Plasma concentration of the drug

Timepoint

17 sampling time included pre-dose (time 0) and at the following hours post-dose: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 24, 48 and 72 h

Method of measurement

Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: This study examines the bioequivalence of Sitagliptin / Metformin tablets produced by a domestic company with a foreign brand sample. We have only one intervention group and there is no control group. The intervention group, which

includes healthy, fasting male volunteers, will receive a single dose, a 50/1000 mg tablet manufactured by the pharmaceutical company Rayhaneh and Janumet brand, in two 72-hour periods with an interval of one week, on the day of the study. And in 17 different time periods up to 72 hours after taking the medicine, blood samples will be taken from the volunteers in the amount of 3 ml each time, that is, a total of 51 ml within 72 hours. The training that will be given to the volunteers includes avoiding the consumption of drinks containing alcohol and xanthine and other interfering drugs in the prescription drug from 48 hours before the start of the study until the end of the study.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Drug Applied Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Hamed Hamishehkar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rayhaneh Pharmaceutical Company

Full name of responsible person

Yahya Khazaei

Street address

2nd floor, No. 5., Parvaneh St., Jalal Al Ahmad, Tehran St

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Tehran

Province

Tehran

Postal code

1439915481

Phone

+98 21 5765 5000

Email

info@rayhanehpharma.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rayhaneh 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

Tabriz University of Medical Sciences

Full name of responsible person

Hamed Hamishehkar

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Hamed Hamishehkar

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address**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

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