Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A study to compare the relative bioavailability of Raha and Merck formulations of metformin 1000 mg tablets in 24 healthy adult male volunteers under fasting conditions

Protocol summary

Study aim
The study aims to compare the bioequivalence study of metformin hydrochloride 1000 mg tablets under fasting conditions

Design
This randomized, single-dose, two-way, crossover study is conducted to compare the relative bioavailability of two formulations of metformin hydrochloride tablets under fasting conditions in 24 healthy adults male volunteers.

Settings and conduct
The dose administration and subsequent sample collection will be performed in Payambar-Azam hospital (Gonbade Kavous, Iran)

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Males, 18-50 years of age (inclusive). 2. The subject is able and willing to provide written informed consent. 3. The subject is available for the entire study period and is willing to adhere to protocol requirements as evidenced by written informed consent. 4. The subject has stable residence and telephone. 5. Good health as determined by lack of clinically significant abnormalities in health assessments performed at screening. Exclusion criteria: 1. History of allergy or history of any drug hypersensitivity or intolerance which, in the opinion of the investigator, would compromise the safety of the subject or the study. 2. Significant history or current evidence of chronic infectious disease, system disorder or organ dysfunction. 3. Presence of gastrointestinal disease or history of malabsorption within the last year. 4. Presence of a medical condition requiring regular treatment with prescription drugs. 5. Use of pharmacologic agents known to significantly induce or inhibit drug-metabolizing enzymes within 30 days prior to dosing.

Intervention groups
Single dose of metformin 1000 mg tablets manufactured by Raha and Merck companies

Main outcome variables
Drug plasma concentration; Area under the plasma concentration-time curve

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130626013776N6**
Registration date: **2018-01-21, 1396/11/01**
Registration timing: **retrospective**

Last update: **2018-01-21, 1396/11/01**
Update count: **0**

Registration date
2018-01-21, 1396/11/01

Registrant information

Name
Hossein Amini

Name of organization / entity
Golestan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 17 1442 1651

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-10-23, 1396/08/01

Expected recruitment end date
2018-01-21, 1396/11/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A study to compare the relative bioavailability of Raha and Merck formulations of metformin 1000 mg tablets in 24 healthy adult male volunteers under fasting conditions

Public title
Bioequivalence study of metformin hydrochloride 1000 mg tablets under fasting conditions
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Males, 18-50 years of age (inclusive). The subject is able and willing to provide written informed consent. The subject is available for the entire study period and is willing to adhere to protocol requirements as evidenced by written informed consent. The subject has stable residence and telephone. Good health as determined by lack of clinically significant abnormalities in health assessments performed at screening.
Exclusion criteria:
History of allergy or sensitivity to metformin hydrochloride history of any drug hypersensitivity or intolerance which, in the opinion of the investigator, would compromise the safety of the subject or the study. Significant history or current evidence of chronic infectious disease, system disorder or organ dysfunction. Presence of gastrointestinal disease or history of malabsorption within the last year. History of psychiatric disorders occurring within the last two years that required hospitalization or medication. Presence of a medical condition requiring regular treatment with prescription drugs. Use of pharmacologic agents known to significantly induce or inhibit drug-metabolizing enzymes within 30 days prior to dosing. Receipt of any drug as part of a research study within 30 days prior to dosing. Donation or significant loss of whole blood (480 ml or more) within 30 days prior to dosing.
Age
From **18 years** old to **45 years** old
Gender
Male

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Table of random numbers was used.
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
Ethics Committee of Golestan University of Medical Sciences
Street address
Gorgan, Shast cola road, Falsafi Building
City
Gorgan
Province
Golestan
Postal code
4916817693
Approval date
2017-12-25, 1396/10/04
Ethics committee reference number
IR.GOUMS.REC.1396.232

Health conditions studied

1

Description of health condition studied
Healthy volunteers
ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Drug plasma concentration
Timepoint
Before intervention and 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12 and 24 h after intervention
Method of measurement
Blood sampling and measurement of drug concentrations by HPLC

2

Description
Area under plasma concentration-time curve
Timepoint
0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12 and 24 h after

intervention

Method of measurement

Blood sampling and measurement of drug concentrations by HPLC

Secondary outcomes

1

Description

Time to reach Cmax

Timepoint

During 4 hours after drug administration

Method of measurement

Blood sampling and drug analysis by HPLC

Intervention groups

1

Description

Intervention group: Single dose of Rahamet (metformin 1000 mg) tablet manufactured by Raha Pharmaceuticals

Category

Treatment - Drugs

2

Description

Intervention group: Single dose of Glucophage (metformin 1000 mg) tablet manufactured by Merck Pharmaceuticals

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Payambar Azam Hospital

Full name of responsible person

Yahya Naseri Fard

Street address

Gonbad-Incheboroun Road Km1

City

Gonbad Kavous

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Phone

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haminhplc@yahoo.com

Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Raha Pharmaceuticals

Full name of responsible person

Dr. Akram Sharifian

Street address

Central Office:No.11, Sofeh Ind. Zone, 7th km of Shiraz Road

City

isfehan

Province

Isfehan

Postal code

81745-567

Phone

+98 31 3654 0659

Fax

+98 31 3654 0183

Email

info@rahapharma.com

Web page address

http://rahapharm.com/home

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Raha Pharmaceuticals

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

2

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Honarvar

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Sari Road Km 2,

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dr.roshandel@goums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan University of Medical Sciences
Proportion provided by this source
1
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Gorgan Bioanalysis Center
Full name of responsible person
Dr. Hossein Amini
Position
Head of Center
Latest degree
Ph.D.
Other areas of specialty/work
Drug Analysis
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Other areas of specialty/work
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Person responsible for updating data

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Other areas of specialty/work
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haminhplc@yahoo.com
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document

The plasma concentration-time profiles of volunteers and other pharmacokinetic data from brand product could be provided.

When the data will become available and for how long

Within 3 months after termination of the study

To whom data/document is available

All academic members could apply for the data.

Under which criteria data/document could be used

These data belong to the principal investigator and could be used only after getting a formal permission from him.

From where data/document is obtainable

Please send your requests by E-mail

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

The applicant should have scientific eligibility

Comments