Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

A study to compare the relative bioavailability of Aramis Pharmed and Merck extended release formulations of metformin 1000 mg tablets in 24 healthy adult volunteers under fasting conditions

Protocol summary

Study aim

The study aims to compare the bioequivalence of metformin 1000 mg extended release tablets under fasting conditions

Design

This randomized, single-dose, two-way, crossover study is conducted to compare the pharmacokinetic of metformin and Glucophage® tablets in 24 healthy adults male volunteers. Volunteers will be sorted and receive a number from 1 to 24. In the first phase of the study, 12 volunteers will receive metformin manufactured by Aramis Pharmed Pharmaceuticals and the remaining 12 volunteers will receive Glucophage® produced by Merck. The administered drugs will be replaced by each other in the second phase of the study. Since in this study, the volunteers will receive both Test and Reference drugs, each volunteer will act as his own control.

Settings and conduct

The dose administration and subsequent sample collection will be performed in S. Motahhari hospital (Gonbade Kavous, Iran).

Participants/Inclusion and exclusion criteria

Males, 18-50 years of age. The subject is available for the entire study period and is willing to adhere to protocol requirements as evidenced by written informed consent. Good health at screening. Exclusion criteria: History of any drug hypersensitivity or intolerance. Significant history or current evidence of chronic disease. Receipt of any drug as part of a research study within 30 days prior to the present study.

Intervention groups

First intervention group: A single oral dose of metformin 1000 mg extended release tablets manufactured by Aramis Pharmed company to 12 subjects. Second intervention group: A single oral dose of metformin 1000 mg extended release tablets manufactured by Merck company to 12 subjects. Since in this study, the volunteers will receive both Test and Reference drugs, each volunteer will act as his own control.

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: **IRCT20130626013776N17**
Registration date: **2019-09-22, 1398/06/31**
Registration timing: **prospective**

Last update: **2019-09-22, 1398/06/31**
Update count: **0**

Registration date

2019-09-22, 1398/06/31

Registrant information

Name

Hossein Amini

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 1442 1651

Email address

hamini@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study to compare the relative bioavailability of Aramis Pharmed and Merck extended release formulations of metformin 1000 mg tablets in 24 healthy adult volunteers under fasting conditions

Public title

Bioequivalence study of metformin 1000 mg extended release tablets under fasting conditions

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Males, 18-50 years of age. The subject is able and willing to provide signed 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. History of any drug hypersensitivity or intolerance which, in the opinion of the investigator,would compromise the safety of the subject of 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 a medical disorders occurring within the last year that required hospitalization or medication. 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 the present study. Donation or significant loss of whole blood (480 ml or more) within 30 days prior to the present study.

Age

From **18 years** old to **50 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **14**

A volume of 3 ml of blood is obtained in each sampling time through a venous cannula

Randomization (investigator's opinion)

Randomized

Randomization description

Each subject is identified by a number from 1 to 24. This number is allocated according to their entrance to volunteers' list in the screening day. Then, the following randomization table is used according to the crossover design of the study. All participants randomized into two sequences of Test/Reference and Reference/Test products Subjects Dosing Sequence Day 1 Day 8 1 R/T Reference Test 2 T/R Test Reference 3 T/R Test Reference 4 R/T Reference Test 5 T/R Test Reference 6 R/T Reference Test 7 R/T Reference Test 8 T/R Test Reference 9 T/R Test Reference 10 T/R Test Reference 11 R/T Reference Test 12 R/T Reference Test 13 T/R Test Reference 14 T/R Test Reference 15 T/R Test Reference 16 R/T Reference Test 17 T/R Test Reference 18 R/T Reference Test 19 R/T Reference Test 20 R/T Reference Test 21 T/R Test Reference 22 T/R Test Reference 23 R/T Reference Test 24 R/T Reference Test

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

Falsafi Building, Sari Road Km 5

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2019-07-21, 1398/04/30

Ethics committee reference number

IR.GOUMS.REC.1398.133

Health conditions studied

1

Description of health condition studied

.

ICD-10 code

ICD-10 code description

Primary outcomes

1

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

2

Description
Area under plasma concentration-time curve
Timepoint
At time zero and 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12 and 24 h after drug administration
Method of measurement
Blood sampling and measurement of drug concentrations by HPLC

Secondary outcomes

1

Description
Plasma half-life
Timepoint
From the terminal 16 hours of plasma concentration-time profile
Method of measurement
Blood sampling and drug analysis by HPLC

Intervention groups

1

Description
Intervention group: Oral administration of a single dose of metformin 1000 mg tablet manufactured by Aramis Pharmed Pharmaceuticals (Slomet) to healthy volunteers under fasting condition in the morning of the experiment day
Category
Treatment - Drugs

2

Description
Intervention group: Oral administration of a single dose of metformin 1000 mg tablet manufactured by Merck Co. (Glucophage) to healthy volunteers under fasting condition in the morning of the experiment day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis Center, S. Motahhari Hospital
Full name of responsible person
Yahya Naserifard
Street address
Taleghani Street
City
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haminhplc@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Aramis Pharmed Pharmaceuticals
Full name of responsible person
Dr. Hosseini
Street address
Unit 1, 1st floor, No. 52, Rahimi St., After Niayesh HW., Vali Asr st.
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Province
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1967915183
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Fax
+98 21 2201 2958
Email
info@aramispharmed.com
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Aramis Pharmed 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

Person responsible for general inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Hossein Amini
Position
Associate professor
Latest degree
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Other areas of specialty/work
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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
Data are confidential and need permission from the company.
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