Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Comparative bioequivalence study of two different Metformin 1000mg formulations (Sobhandarou Pharmaceutical Company & reference) in 24 Iranian volunteers

Protocol summary

Study aim
Evaluation of bioequivalence of a 1000 mg Metformin tablet manufactured by Sobhan Darou Pharmaceutical Company with its reference sample

Design
Bioequivalency study of Metformin 1000 mg tablet (Sobhan darou Pharmaceutical Company) and reference product of Glucophage in 24 healthy volunteers. This study was cross-over, random, and double-blind. Excel rand function was used for randomization

Settings and conduct
This study is carried out in the central laboratory of the Hamadan School of Pharmacy. The 24 volunteers are randomly divided into two groups and are divided into two stages of the study. This study is double-blind and the recipient and analyzer will not be in the process of consuming the product. Blood samples will be collected from each volunteer at specified times for 24 hours. The method used to measure the amount of drug in the samples of volunteers will be performed using high-performance liquid chromatography and an infrared detector.

Participants/Inclusion and exclusion criteria
Ages 18 to 45 years, Actual weight (TBW) in the range of 20% IBW, Non-smoker

Intervention groups
Sustained release tablets of metformin formulated at Sobhandarou Pharmaceutical company 2. Sustained release tablets of metformin formulated at Merck company (Glucophage)

Main outcome variables
Metformin plasma concentration; Area under the curve; Half-life time; Time to reach maximum plasma concentration; Maximum concentration

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20111107008022N9**
Registration date: **2022-11-28, 1401/09/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-28, 1401/09/07**
Update count: **0**

Registration date
2022-11-28, 1401/09/07

Registrant information

Name
Katayoun Derakhshandeh

Name of organization / entity
Hamadan University of Medical Sciences, Pharmacy school

Country
Iran (Islamic Republic of)

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+98 81 3838 1590

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kderakhshandeh@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-22, 1401/09/01

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative bioequivalence study of two different Metformin 1000mg formulations (Sobhandarou Pharmaceutical Company & reference) in 24 Iranian volunteers

Public title
Bioequivalence study of two different Metformin formulations

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy male and female volunteers Aged 18 to 45 years Based on laboratory safety tests, no history of diseases affecting drug pharmacokinetic processes lack of any chronic or acute medication at least 1 week before the start of the study Actual weight (TBW) in the range of 20% IBW

Exclusion criteria:
Subject showed clinically relevant deviations from normal in physical examination Subject had undergone surgery of the gastrointestinal tract Subject had donated a unit of blood or participated in another clinical trial, within the last three months before the first treatment Subject had a history of alcohol abuse or smokes more than 10 cigarettes per day Use any medication within 14 days before the first treatment A history of allergic to biguanides

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 24 volunteers were randomly divided into two groups of 12 test (A) and reference (B) drug recipients by Excel software, then in the second phase, groups A and B will be cross-referenced to the test and drug recipients.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this project, the volunteers, person responsible for blood sampling and analyzer are kept blind. To blind these people, all the information collected is coded to the researcher, and after the analysis is completed, codes will be opened.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committees of Hamadan University of Medical Sciences

Street address
School of Pharmacy, Hamadan University of Medical Sciences, Beside Mardom amusement Park, Shahid Fahmideh Blvd, Hamadan , Iran

City
Hamadan

Province
Hamadan

Postal code
6517838678

Approval date
2022-10-22, 1401/07/30

Ethics committee reference number
IR.UMSHA.REC.1401.627

Health conditions studied

1

Description of health condition studied
Health and normal volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Drug plasma concentration

Timepoint
Blood samples were collected at 0, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10, 12 and 24 hour following drug administration

Method of measurement
Using High Performance Liquid Chromatography instrument

Secondary outcomes

1

Description
Pharmacokinetic parameters

Timepoint

0; 0.5; 1.0; 2.0; 3.0; 4.0; 4.5; 5.0; 5.5; 6.0; 6.5; 7.0; 8.0; 9.0; 10.0; 12.0; 16.0; 20.0; 24.0; 30.0 and 36 hours post-dose

Method of measurement

Drug analysis in plasma using a chromatographic apparatus and calculating pharmacokinetic parameters using pharmacokinetic models

Intervention groups

1

Description

Intervention group: Single dose of Glucophage 1000 mg tablet manufactured by Merck Pharmaceutical company in 24 healthy volunteers

Category

Treatment - Drugs

2

Description

Control group: Single dose of Metformin 1000 mg tablet manufactured by Sobhandaru Pharmaceutical company in 24 healthy volunteers

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Pharmacy, Hamadan University of Medical Sciences

Full name of responsible person

Katayoun Derakhshandeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sobhandarou

Full name of responsible person

Ali Mortazavi

Street address

industrial city of Rasht- Rasht

City

Rasht

Province

Guilan

Postal code

413351958

Phone

+98 21 6656 8181

Email

info@sobhandarou.com

Web page address

https://www.sobhandarou.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sobhandarou

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr.Katayoun Derakhshandeh

Position

Professor of Pharmaceutics

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific

inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is 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 pharmacokinetic data obtained from the study are for each volunteer in both the test and reference groups.

When the data will become available and for how long
6 months after the end of the study

To whom data/document is available
All researchers and clinical specialists

Under which criteria data/document could be used
There is no denial of access to data

From where data/document is obtainable
The results of the project are reported in the form of a published paper. Article will be available after it is published. If needs quicker access to the results, can reach us at "k.derakhshandeh@umsha.ac.ir"

What processes are involved for a request to access data/document
There will be no problem accessing results when publishing results in online articles. The wait time to access the results will be 3 months after the project is completed. If needs quicker access to the results, can reach us at "k.derakhshandeh@umsha.ac.ir".

Comments