Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim
This study, as part of the curriculum of bioequivalence tests of domestic production, evaluates the bioequivalence of a 1000 mg Metformin tablet manufactured by Reihaneh Pharmaceutical Company with its reference sample

Design
Bioequivalency study of Metformin 1000 mg tablet (Reihaneh Pharmaceutical Company) and reference product of Glucophage are evaluated in 24 healthy volunteers. This study was cross-over, random, and double-blind.

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, Real weight (TBW) in the range of +-20% ideal weight, Non-smoker

Intervention groups
Sustained release tablets of metformin formulated at Reihaneh 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: **IRCT20111107008022N7**
Registration date: **2021-06-26, 1400/04/05**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-26, 1400/04/05**
Update count: **0**

Registration date
2021-06-26, 1400/04/05

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2021-12-22, 1400/10/01

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 (Reihaneh Pharmaceutical Company & reference) in 24 Iranian volunteers

Public title
Bioequivalency study of two different Metformin formulations

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
24 healthy male and female volunteers will participate in this study 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 Adherence to the criteria on the basis of moral obligation and signed an informed consentactual 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 gastro-intestinal 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 **45 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **24**
Each participant in each study period will receive a single dose of test and reference formulations

Randomization (investigator's opinion)
Randomized

Randomization description
Each volunteer is identified by the number 1 to 24. The number assigned to each volunteer is based on the priority of being on the list when screening. Due to the cross-sectional study, 24 participants were assigned to test and reference products (groups A and B), respectively, using the Excel program rand command. Then, in the second stage, groups A and B will receive cross-reference and test drugs crosswise.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, 24 volunteers were randomly divided into two groups of 12 test (A) and reference (B) drug recipients by Excel software. 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

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Hamadan

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6517838678

Approval date
2021-06-12, 1400/03/22

Ethics committee reference number
IR.UMSHA.REC.1400.237

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 h following drug administration

Method of measurement

Using HPLC instrument

Secondary outcomes

1

Description
Pharmacokinetic parameters: Half-life, Cmax The peak plasma concentration of a drug after administration, The volume of distribution, and Clearance
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: Control group: Single dose of Metformin 1000 mg tablet manufactured by Reihaneh 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
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Sponsors / Funding sources

1

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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Reihaneh 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
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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