

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative bioequivalence study of two different Metformin 750mg formulations (Koushan pharmed & 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 750 mg Metformin slow-release tablet manufactured by Kushan pharmed Pharmaceutical Company with its reference sample.

Design

Bioequivalency study of Metformin 750 mg tablet (Koushan pharmed co.) and reference product of Glucophage are evaluated in 24 healthy volunteers. This study was cross-over, open, random, and a single-blind.

Settings and conduct

This study is carried out at the central lab, Hamedan faculty of pharmacy. Twenty-four volunteers are randomly divided into two groups and are divided into two periods. This study is single-blind, and the volunteers and analyst will not know the type of product used. Blood samples were collected at a specified time and for 24 hours from each of the volunteers and then serum separated at room temperature using a centrifuge and stored at -20°C. The method used to measure the amount of drug in samples using high-performance liquid chromatography and an infrared detector. The analysis method validation, will also be carried out. Finally, using the obtained data analysis, the pharmacokinetic parameters are calculated.

Participants/Inclusion and exclusion criteria

Healthy male subjects aged between 18 and 45 years; Normal physical examination at the screening visit; No history of diseases affecting the pharmacokinetics of the drug; Any drug intake within two (2) week prior to the study; Understanding of the study and agreement to give written informed consent; Having the Body Mass Index which is in the desirable range (+/-20%IBW); Nonsmokers

Intervention groups

Bioequivalency study of Metformin tablet (Koushan pharmed co.) compare to reference product of 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: **IRCT20111107008022N5**

Registration date: **2019-03-15, 1397/12/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-15, 1397/12/24**

Update count: **0**

Registration date

2019-03-15, 1397/12/24

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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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-21, 1397/09/30

Expected recruitment end date

2019-04-18, 1398/01/29

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative bioequivalence study of two different Metformin 750mg formulations (Koushan pharmed & reference) in 24 Iranian volunteers

Public title
Bioequivalency study of two different Metformin formulations

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion 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 consent; actual weight (TBW) in the range of 20% IBW
Exclusion criteria:
Age outside the range mentioned; acute or chronic smoking or alcohol, failure to obtain any of the above health tests, medication two weeks before the experiment

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: **1**
Each participant in each study period will receive a single dose of Metformin

Randomization (investigator's opinion)
Randomized

Randomization description
In the first period, the test and the reference drug are randomly divided into two groups of 12 (group A and B), then in the second period, in the cross over form, the groups A and B will be received reference and test drug.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the volunteers, according to the predetermined random table that is available to the researcher, are in one of the groups receiving the test and reference drug. To blind the analyst and volunteers,

the information collected from the drug concentration in the plasma of them is encoded and will be unlocked the codes after completion of the analysis.

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

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6517838678

Approval date

2018-10-12, 1397/07/20

Ethics committee reference number

IR.UMSHA.REC.1397.452

Health conditions studied

1

Description of health condition studied

Health and normal volunteers

ICD-10 code

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ICD-10 code description

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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

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 Metformin 750 mg tablet manufactured by Koushan Pharmmed
Pharmaceutical company in 24 healthy volunteers

Category

Treatment - Drugs

2

Description

Intervention group: Single dose of Glucophage 750 mg tablet manufactured by Merck 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

Sponsor

Name of organization / entity

Kushan Pharmmed Company

Full name of responsible person

Dr. Alireza Saei

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Email

mardani@koushanpharmed.com

Web page address

<http://www.koushanpharmed.com>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kushan Pharmmed 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

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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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

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

If results are published in online articles, there will be no problem accessing the results

Comments