

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Bio equivalence study of metformin 500 mg tablets manufactured by Sana Med pharmaceutical company on 24 healthy volunteers and comparing pharmacokinetics results with Glucophage tablets manufactured by MERCK.

Protocol summary

Study aim

Comparing pharmacokinetics parameters of Sana Med metformin 500 mg tablets and Glucophage 500 mg tablet of Actoverco company.

Design

Bioequivalence study insists of one 24 healthy volunteers group. This group itself randomly divided to two 12 volunteers sub-groups. The first sub-group administered reference drug and the second sub-groups administered generic or test drugs. The bioequivalence study is performed as cross over double blind whitin 1-2 weeks.

Settings and conduct

Bioequivalence metformin 500mg study will be performed under physician since 7 AM until 7 PM . This study is carried out as a cross over double blind investigation. The blind person included volunteers, administrator and analyst.

Participants/Inclusion and exclusion criteria

Acceptance criteria: Healthy liver and kidney and observing BMI limits. Rejection criteria: smokers and pregnancy

Intervention groups

Intervention group insist Measuring maximum plasma concentration and Tmax concentration. Control group include the volunteers administrated reference drugs and Measuring maximum plasma concentration and Tmax concentration.

Main outcome variables

Most important outcome is plasma concentration versus time profile. Pharmacokinetics parameters are calculated using this profile and included Cmax, Tmax , AUC 0-t and AUC 0-inf

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200513047423N1**

Registration date: **2020-06-24, 1399/04/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-24, 1399/04/04**

Update count: **0**

Registration date

2020-06-24, 1399/04/04

Registrant information

Name

Amir Mehdizadeh

Name of organization / entity

Ofogh pajo

Country

Iran (Islamic Republic of)

Phone

+98 21 6673 8727

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-15, 1399/03/26

Expected recruitment end date

2020-06-26, 1399/04/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bio equivalence study of metformin 500 mg tablets manufactured by Sana Med pharmaceutical company on 24 healthy volunteers and comparing pharmacokinetics results with Glucophage tablets manufactured by MERCK.

Public title

Bio equivalence study of metformin 500 mg

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy liver Healthy kidney observing BMI

Exclusion criteria:

Out of age ranges No smoker unhealthy liver and kidney pregnancy

Age

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

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **1**

Each volunteer has been administered once reference drug and the next time test drugs .

Randomization (investigator's opinion)

Randomized

Randomization description

We designate to 24 healthy volunteers one number between 1 and 24 . Extraction of 12 numbers is carried out using random number table available in internet. These first 12 numbers establish first group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The main investigator creates a table using randomization and divides 24 healthy volunteer in 2 groups which only he knows the details of group. Test and reference drugs are packaged in special envelopes that administrator and volunteers are blinded regarding to the kind of drugs. Volunteers, administrator (health care professional) and analyst are blinded regarding to reference and test drugs.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of school of pharmacy and Nursing & midwifery- shahid beheshti university of medical sciences

Street address

No. 65, Razi Ave, Enghelab Sq

City

tehran

Province

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Postal code

1133713144

Approval date

2020-03-02, 1398/12/12

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.303

Health conditions studied

1

Description of health condition studied

Bioequivalence metformin 500 mg

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Increasing plasma concentration after administration of metformin tablets till Tmax and then decreasing plasma concentration after Tmax

Timepoint

Initial blood sampling is performed before drug administration to obtain blank plasma chromatogram of each healthy volunteers. Hence the Tmax of metformin is between 1.5 and 3 hours, so it is needed to have 5 blood samplings before Tmax. This period of time is called absorption phase. In the elimination phase (after Tmax) blood sampling carry out each hours. As in some articles it is mentioned that Tmax of metformin is around 3 hours so the blood samples should be collected in 24 hours.

Method of measurement

In this study, the variable is plasma concentration of metformin. High performance liquid chromatography is used to determine the concentration of metformin in plasma.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: One metformin 500 mg tablet manufactured by Sana Med company (Test drug) is administrated to each of 12 healthy volunteers of group 1 .

Category

Treatment - Drugs

2

Description

Intervention group 2: One Glucophage 500 mg tablet manufactured by ACTOVERCO company under the license of MERCK is administrated to each of 12 healthy volunteers of group 2.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ofoq pharmed

Full name of responsible person

Dr Amir mehdizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sana Med

Full name of responsible person

Dr Malek marzban

Street address

No 1 , Hekmat Ave, Bozorgmehr Ave, valiasr Ave

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Phone

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Email

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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

Sana Med

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Ofoqh pharmed labratory

Full name of responsible person

Dr Amir mehdizadeh

Position

Responsible pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Professor

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Ph.D.

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Person responsible for updating data**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

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

Demography tables of volunteers including group 1 and 2 have been shared in bioequivalence report.

When the data will become available and for how long

The results of bioequivalence study of metformin tablets will be shared after accepting by Iranian food and drug organization.

To whom data/document is available

The results of bioequivalence study of metformin tablets will be accessed by expert by Iranian food and drug organization and financial supporter.

Under which criteria data/document could be used

To promotion of result of investigation, the results will be shared with eager.

From where data/document is obtainable

1-Iranian food and drug organization 2- Ofogh pharmed research laboratory

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

To complied of educational filed of eager to result of investigation.

Comments