Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Bioequivalence study of Metformin 500mg tablet manufactured by Ronak Pharm versus originator brand in healthy volunteers in the fasted and fed conditions

Protocol summary

Study aim
Bioequivalence Study of Metformin 500 mg tablet (Ronophage)manufactured by Ronak Pharm company versus originator brand (Glucophage XR) manufactured by Merck

Design
Bioequivalence study, crossover, single-blinded, 36 healthy volunteers. Simple randomization was used for randomization

Settings and conduct
The study is a single-blinded, cross-over and fasting, and on four series of healthy volunteers. The study will be done in two periods (24h). The interval between these two periods is a week. In the first round of the study, the candidates divide into four groups. the first group receives a test tablet and the second group receives a brand tablet in fasted condition and the third group receives a test tablet and the forth group receives a brand tablet in fed condition . Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. These steps are performed in Radin laboratory in Tabriz

Participants/Inclusion and exclusion criteria
Inclusion criteria: General Health (Liver, Heart, and Kidney); Body Mass Index (18-28); Informed consent; age (18-55 years old). Exclusion criteria: smoking; history of cardiovascular disease; history of liver and kidney disease; alcohol and drug addiction; history of allergy to Metformin

Intervention groups
Intervention group 1: Glucophage XR-500mg tablet as a reference Intervention group 2: Ronophage 500 mg tablet as a test

Main outcome variables
Maximum drug concentration; time to reach maximum drug concentration; half-life of drug

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200623047902N27**
Registration date: **2023-03-19, 1401/12/28**
Registration timing: **prospective**

Last update: **2023-03-19, 1401/12/28**
Update count: **0**

Registration date
2023-03-19, 1401/12/28

Registrant information

Name
Elham Ghasemian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6696 5196

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ghasemian@zistdaru.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2024-03-18, 1402/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bioequivalence study of Metformin 500mg tablet manufactured by Ronak Pharm versus originator brand in healthy volunteers in the fasted and fed conditions

Public title
Bioequivalence study of Metformin 500mg tablet

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
General Health (Liver, Heart, and Kidney) Body Mass Index (18-28) Informed consent Age (18-55 years old)

Exclusion criteria:
Smoking History of cardiovascular disease History of liver and kidney disease Alcohol and drug addiction History of allergy to Metformin

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked

- Participant

Sample size
Target sample size: **36**
More than 1 sample in each individual
Number of samples in each individual: **36**
Blood sample

Randomization (investigator's opinion)
Randomized

Randomization description
People in the mentioned age group are invited to participate through the advertisement. People are then checked for health and healthy volunteers are identified. Each candidate is assigned a number from 1 to 36. The numbers are written on a plastic ball, poured into a container, and mixed. The balls are then removed randomly from the container. The first 9 no.s are considered as (first sequence: Ronak Pharm's medicine in fasting condition) and the second 9 no.s are considered as (second sequence: originator brand recipient in fasting condition)The third 9 no.s are considered as (third sequence: Ronak Pharm's medicine in fed condition) and the forth 9 no.s are considered as (forth sequence: originator brand recipient in fed condition). The volunteers don't have any information about taking the test drug or brand drug

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a single-blinded clinical trial (volunteers). Ronak Pharm's Metformin and Originator brand tablets are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test dosage form

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Tabriz University of Medical Sciences

Street address
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street,

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Approval date
2023-02-20, 1401/12/01

Ethics committee reference number
IR.TBZMED.REC.1401.1062

Health conditions studied

1

Description of health condition studied
This study is performed on healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The plasma concentration of the drug

Timepoint
Pre-dose, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12, and 24 h after drug administration

Method of measurement
Liquid Chromatography Mass-Mass

Secondary outcomes

1

Description
Time to reach maximum plasma concentration

Timepoint
After intervention

Method of measurement
The time to reach the maximum drug concentration in plasma is recorded

2

Description
Extent of absorption
Timepoint
After intervention
Method of measurement
Calculation of area under curve of concentration -time

Intervention groups

1

Description
Intervention group: single dose, one oral tablet of Glucophage- XR 500mg manufactured by Merck, as a reference product
Category
Treatment - Drugs

2

Description
Intervention group: Single dose, one oral tablet of Ronophage 500 mg manufactured by Ronak Pharm company as a test product
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Radin Laboratory
Full name of responsible person
Javad Shokri
Street address
No.22, first floor, Azadi alley, Moalem st., Abureihan St
City
Tabriz
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5154995671
Phone
+98 914 313 5843
Email
Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ronak Pharm company
Full name of responsible person
Saeed Maleki
Street address
No. 22, No. 22, Mollasadra St., Sheik Bahai Shamal St., Arafi Shirazi St., Vanak Square,
City
Tehran
Province
Tehran
Postal code
1993644514
Phone
+98 21 9107 9170
Email
info@ronakpharm.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ronak Pharm 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
Islamic Azad University
Full name of responsible person
Elham Ghasemian
Position
Visiting professor
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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
These data are as secure between researchers and related industries.

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