Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

In vivo Fasted-State Bioequivalence Study of Rosuvastatin 40 mg Tablet Compared to Innovator Product

Protocol summary

Study aim

In vivo Fasted state Bioequivalence study of Rosuvastatin 40 mg tablet compared to innovator product

Design

Twenty-four healthy male volunteer will enter the study based on random numbers table as two groups of twelve people. Each volunteer will receive a single dose of drug in two periods. In one period the test formulation and in another period the reference formulation (without knowing the formulation identity in each period). Therefore, each volunteer will be his own "Control".

Settings and conduct

After administration of one 40mg tablet to volunteer, the blood samples will be taken in predetermined time intervals up to 48 hours. The samples will be stored in freezer -4 degrees centigrade until analysis and sample quantitation. In this study the volunteer would not be aware of the formulation identity in each period

Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (Liver, Heart and Kidney), Age (18-60) Exclusion criteria: Smoking, History of cardiovascular disease, liver and kidney disease, Pregnancy, Alcohol and drug addiction, History of drug allergy

Intervention groups

Intervention group will receive one test drug product. Blood samples will be taken from the volunteers for 48 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography with mass spectroscopy detector. Control group will receive one reference drug product. Blood samples will be taken from the volunteers for 48 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography with mass spectroscopy detector.

Main outcome variables

Drug plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210519051345N11**
Registration date: **2022-05-12, 1401/02/22**
Registration timing: **prospective**

Last update: **2022-05-12, 1401/02/22**
Update count: **0**

Registration date

2022-05-12, 1401/02/22

Registrant information

Name

Parvin Zakeri-Milani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 8801

Email address

pzakeri@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-20, 1401/02/30

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In vivo Fasted-State Bioequivalence Study of Rosuvastatin 40 mg Tablet Compared to Innovator Product

Public title
Investigating In vivo Bioequivalence of Rosuvastatin Tablet
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
General Health (Liver, Heart and Kidney)
Exclusion criteria:
Smoking, History of cardiovascular disease, liver and kidney disease, Pregnancy, Alcohol and drug addiction, History of drug allergy
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
The order of receiving the test product or reference for each subject in each time period will be determined based on the randomization program. The randomization program will be developed using randomization software based on the number assigned to each subject. The number assigned to each subject will be based on the priority of being on the list of subjects for screening.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, Volunteers participating will be blinded to the type of product they are taking in each period (test or reference product). This means that the product will be given to the volunteers for administration outside the original packaging
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Biomedical Research Committe, Tabriz University of Medical Sciences
Street address
Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishabouri st., Golgasht.
City
Tabriz
Province
East Azarbaijan
Postal code
51664-14766
Approval date
2022-05-11, 1401/02/21
Ethics committee reference number
IR.TBZMED.REC.1401.127

Health conditions studied

1

Description of health condition studied
In the present study, no diseases will be examined and products will be administered by healthy volunteers.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma Drug Concentration
Timepoint
.5-48 hours in predetermined time intervals after drug administration
Method of measurement
HPLC (High performance liquid chromatography)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group will receive one test drug product. Blood samples will be taken from the volunteers for 48 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography with mass spectroscopy detector.
Category
Treatment - Drugs

2

Description
Control group: Control group will receive one reference drug product. Blood samples will be taken from the volunteers for 48 hours at the mentioned times after drug administration and the concentration of drug in

blood samples will be measured by liquid chromatography with mass spectroscopy detector.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Pharmacy, Tabriz University of Medical Sciences

Full name of responsible person

Parvin Zakeri-Milani

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Tabriz University of Medical Sciences, Faculty of Pharmacy, Golgasht st Attar Neishaboori st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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No.2 Central Building 3rd Floor, Daneshgah st. Tabriz University of Medical Sciences

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Grant name

Grant code / Reference number

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

No

Title of funding source

Kimidaru Pharmaceutical Co.

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parvin Zakeri-Milani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Parvin Zakeri-Milani

Position

Professor

Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable