

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 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 Committee, 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****Name of organization / entity**

Tabriz University of Medical Sciences

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Parvin Zakeri-Milani

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Parvin Zakeri-Milani

**Position**

Professor of Biopharmacy and Pharmacokinetics

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Phone****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