

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### In vivo bioequivalence study of Azithromycin 500 mg tablet manufactured by Fatak shimin Co. in comparison to innovator product Zithromax®

#### Protocol summary

##### Study aim

Investigating In vivo bioequivalence of Azithromycin 500 mg tablet manufactured by Fatak shimi Co. in comparison to innovator product Zithromax®

##### Design

Twenty-four healthy 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 by cross-over design. In one phase the test formulation and in next phase the reference formulation (without knowing the formulation identity in each period). The groups will be assigned to test or reference drug randomly by lottery method. Therefore, each volunteer will be his own "Control".

##### Settings and conduct

After administration of one 500 mg tablet to volunteer, the blood samples will be taken in predetermined time intervals up to 72 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 (20-60) Exclusion criteria: Smoking, history of cardiovascular disease, history of liver and kidney disease, pregnancy, alcohol and drug addiction, history of drug allergy

##### Intervention groups

Test group: Administrating the test product and control group: Administrating the innovator product. In the first period, one group of volunteers will receive a single dose of Azithromycin 500 mg generic tablet (test formulation) and the second group will receive a single dose of the reference formulation of the same drug. After one week wash-out period, by cross-over design, the first group and second group will administer the reference and test formulations, respectively.

##### Main outcome variables

Drug plasma concentration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210519051345N4**

Registration date: **2021-10-29, 1400/08/07**

Registration timing: **prospective**

Last update: **2021-10-29, 1400/08/07**

Update count: **0**

##### Registration date

2021-10-29, 1400/08/07

##### 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

2021-12-01, 1400/09/10

##### Expected recruitment end date

2022-01-05, 1400/10/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

In vivo bioequivalence study of Azithromycin 500 mg tablet manufactured by Fatak shimin Co. in comparison to innovator product Zithromax®

**Public title**

Bioequivalence study of Azithromycin 500 mg tablet

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

General Health (Liver, Heart and Kidney), Age (20-60)

**Exclusion criteria:**

Smoking, history of cardiovascular, liver and kidney disease, pregnancy, alcohol and drug addiction, history of drug allergy

**Age**

From **20 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**

A table of random numbers will be used. Random number tables are generated by computers that randomly set the numbers. First, a two-digit code (according to the number of volunteers, which is 24) is given to each candidate, and after creating the table, a random selection of numbers is made. To select sample people from the table, randomly start from a point in the table moving in the direction of the row or column. The selection of the point can be done by closing the eyes and placing a finger or the tip of a pen on the table. Moving in the direction of the row or column does not make any difference and this is optional. After this, the path numbers are controlled, which will be dealt with two types of numbers, one of which is smaller than the volume of the population of the study and the other is larger than the number of the population. Only smaller numbers should be considered and selected. The selected number is actually the individual code that is selected as the sample. This should be continued until enough small number can be selected based on the number of volunteers. The selected individuals are placed in groups one and two. The lottery method is used to assign test drug or reference drug to groups.

**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**

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

51664-14766

**Approval date**

2021-10-25, 1400/08/03

**Ethics committee reference number**

IR.TBZMED.REC.1400.664

**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**

0.5-72 hours in predetermined time intervals after drug administration (0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10, 24, 48, 72 h)

**Method of measurement**

HPLC

**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 72 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 72 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

**Street address**

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

51664-14766

**Phone**

+98 41 3334 8801

**Email**

pzakeri@tbzmed.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mohammad Sameie

**Street address**

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

51664-14766

**Phone**

+98 41 3334 8801

**Email**

pzakeri@tbzmed.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Fatak Shimi Pars Co.

**Proportion provided by this source**

100

**Public or private sector**

Public

**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**

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

**Street address**

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

51664-14766

**Phone**

+98 41 3334 8801

**Email**

pzakeri@tbzmed.ac.ir

**Person responsible for scientific 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

**Street address**

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

51664-14766

**Phone**

+98 41 3334 8801

**Email**

pzakeri@tbzmed.ac.ir

**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

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

51664-14766

**Phone**

+98 41 3334 8801

**Email**

pzakeri@tbzmed.ac.ir

**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**

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