

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### In vivo fasted-state bioequivalence study of Azithromycin 500 mg capsule compared to innovator product

#### Protocol summary

##### Study aim

In vivo fasted-state bioequivalence study of Azithromycin 500 mg capsule

##### Design

Twenty-four healthy male volunteers will participate in the study as two twelve-person study groups. 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 (as blinded). Therefore, each volunteer will be his own "Control".

##### Settings and conduct

After administration of one 500-mg capsule to volunteer, the blood samples will be collected 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 volunteers will be blinded to the type of product they are taking in each period.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (in terms of Liver, Heart and Kidney), Age (18-60 years old) Exclusion criteria: Smoking, History of cardiovascular, 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 72 hours at the mentioned time points after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector. Control group will receive one reference drug product. Blood samples will be taken from the volunteers for 72 hours at the mentioned time points after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector.

##### Main outcome variables

Drug plasma concentration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210519051345N12**

Registration date: **2022-07-26, 1401/05/04**

Registration timing: **prospective**

Last update: **2022-07-26, 1401/05/04**

Update count: **0**

##### Registration date

2022-07-26, 1401/05/04

##### 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

2022-10-23, 1401/08/01

##### Expected recruitment end date

2023-01-20, 1401/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

In vivo fasted-state bioequivalence study of Azithromycin 500 mg capsule compared to innovator product

#### Public title

Investigating the in vivo bioequivalence of Azithromycin 500 mg capsule

#### Purpose

Other

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

General Health (in terms of 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

To randomly assign participants in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope. Numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

In this study, volunteers 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 outside its 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

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

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

51664-14766

#### Approval date

2022-06-01, 1401/03/11

#### Ethics committee reference number

IR.TBZMED.REC.1401.204

### Health conditions studied

#### 1

##### Description of health condition studied

In the present study, the products will be administered to healthy volunteers.

##### ICD-10 code

##### ICD-10 code description

### Primary outcomes

#### 1

##### Description

Plasma concentration of drug

##### Timepoint

0.5-72 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 a single test drug product. Blood samples will be collected for 72 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector

##### Category

Treatment - Drugs

#### 2

##### Description

Control group: Control group will receive a single reference drug product. Blood samples will be collected for 72 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography

equipped 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**

Faculty of Pharmacy, University of Medical Sciences, Goltasht st., Attar Neishaboori st.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

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**Phone**

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**Email**

pzakeri@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Parviz Shahabi

**Street address**

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

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shahabip@tbzmed.ac.ir

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

No

**Title of funding source**

Tolid Daru Pharmaceutical 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**

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

**Street address**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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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