# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## In vivo Fasted state Bioequivalence study of Azithromycin 250 mg tablet in comparison to innovator product

## Protocol summary

**Study aim**
Investigating in vivo bioequivalence of azithromycine 250 mg tablet

**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 250 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 (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 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. 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.

**Main outcome variables**
Drug plasma concentration

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20210519051345N9**
Registration date: **2022-02-07, 1400/11/18**
Registration timing: **prospective**

Last update: **2022-02-07, 1400/11/18**
Update count: **0**

**Registration date**
2022-02-07, 1400/11/18

**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**
2022-02-09, 1400/11/20

**Expected recruitment end date**
2022-03-11, 1400/12/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

In vivo Fasted state Bioequivalence study of Azithromycin 250 mg tablet in comparison to innovator product

**Public title**
In vivo bioequivalence study of Azithromycin 250 mg 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**
A table of random numbers will be used. 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 Committe, Tabriz University of Medical Sciences

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

**City**
Tabriz

**Province**
East Azarbaijan

**Postal code**
51664-14766

**Approval date**
2022-02-02, 1400/11/13

**Ethics committee reference number**
1123.IR.TBZMED.REC.1400

## 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**
Drug plasma concentration

**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 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**

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

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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, Daneshgah st. Tabriz University of Medical Sciences

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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**

Keyhan Daroo 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

**Street address**

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## Person responsible for scientific inquiries

**Contact**

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Tabriz University of Medical Sciences

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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