

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 azithromycin 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 Committee, 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.
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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
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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

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

Tabriz University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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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