Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Committe, 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, Golgasht st., Attar Neishaboori st.

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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

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

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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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