Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Committe, 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.

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Tabriz

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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.

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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.

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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

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