

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Investigating in vivo bioequivalence of Azithromycin 200 mg/5 ml suspension compared to innovator product Zithromax®

#### Protocol summary

##### Study aim

In vivo bioequivalence study of Azithromycin 200 mg/5 ml suspension

##### Design

The clinical trial has control and test groups with crossover, randomized design, without blinding. Twenty-four healthy volunteers will participate randomly in the study as two twelve-person study groups. Each volunteer will receive a single dose of drug in two periods. Therefore, each volunteer will be his own "Control". To randomly assign participants in two groups, the lottery method will be used.

##### Settings and conduct

After oral administration of 5 ml Azithromycin suspension 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. The concentration of drug in blood samples will be measured by liquid chromatography. The study will be performed in Tabriz University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (in terms of Liver, Heart and Kidney), Age (18-59 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 a single oral dose of test product (5 ml of Azithromycin suspension of Keyhan Darou) and Control group will receive a single dose of reference product (5 ml of Azithromycin suspension of Fizer). Blood samples will be taken for 72 hours at the mentioned time points after drug administration and the plasma will be stored in freezer until analysis.

##### Main outcome variables

Drug plasma concentration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210519051345N42**

Registration date: **2023-12-30, 1402/10/09**

Registration timing: **prospective**

Last update: **2023-12-30, 1402/10/09**

Update count: **0**

##### Registration date

2023-12-30, 1402/10/09

##### 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

2024-01-07, 1402/10/17

##### Expected recruitment end date

2024-09-10, 1403/06/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating in vivo bioequivalence of Azithromycin 200 mg/5 ml suspension compared to innovator product Zithromax®

**Public title**

Bioequivalence study of Azithromycin Suspension

**Purpose**

Other

**Inclusion/Exclusion criteria****Inclusion criteria:**

General Health (in terms of Liver, Heart and Kidney) Age (18-59 years)

**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 **59 years** old

**Gender**

Both

**Phase**

Bioequivalence

**Groups that have been masked**

*No information*

**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)**

Not blinded

**Blinding description****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, Tabriz University of Medical Sciences, Attar Neishaboori st., Golgasht st.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

51664-14766

**Approval date**

2023-12-18, 1402/09/27

**Ethics committee reference number**

IR.TBZMED.REC.1402.692

**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 oral dose of test product (Azithromycin suspension manufactured by Keyhan Darou) in fasted state. 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 stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively

**Category**

Treatment - Drugs

**2****Description**

Control group: Control group will receive a single oral dose of reference product (Azithromycin suspension manufactured by Fizer) in fasted state. 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 stored in freezer until analysis. Breakfast and lunch will be served two and six hours

after drug administration, respectively.

**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, Tabriz University of Medical Sciences, Attar Neishaboori st., Golgasht st.

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**Province**

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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, Tabriz University of Medical Sciences, Daneshgah st.

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Tabriz

**Province**

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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 Darou 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**

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**

Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaboori street, Golgasht street

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

Tabriz University of Medical Sciences

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Professor

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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**

Not applicable

**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