Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

In vivo bioequivalence study of Azithromycin 250 mg capsule manufactured by Ani Darman Co. compared with Zithromax®

Protocol summary

Study aim
Investigating the bioequivalence of Azithromycin 250 mg capsule compared to innovator product

Design
Twenty-four healthy male volunteers will participate in the study randomly 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 will be received. Therefore, each volunteer will be his own "Control".

Settings and conduct
After administration of single dose of each formulation, 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.

Participants/Inclusion and exclusion criteria
General Health (in terms of Liver, Heart and Kidney), Age (18-59 years old)

Intervention groups
Test group: Receiving the test product Control group: Receiving the innovator product

Main outcome variables
Plasma concentration of drug

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210519051345N13**
Registration date: **2022-08-15, 1401/05/24**
Registration timing: **prospective**

Last update: **2022-08-15, 1401/05/24**
Update count: **0**

Registration date
2022-08-15, 1401/05/24

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
2022-09-11, 1401/06/20

Expected recruitment end date
2023-03-11, 1401/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
In vivo bioequivalence study of Azithromycin 250 mg capsule manufactured by Ani Darman Co. compared with Zithromax®

Public title
Investigating the in vivo bioequivalence of Azithromycin 250 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 disease 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 placed in group A and numbers 13-24 will be placed in group B. Group A will receive intervention 1 (test product) and group B will receive intervention 2 (innovator product), 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 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

2022-08-01, 1401/05/10

Ethics committee reference number

IR.TBZMED.REC.1401.403

Health conditions studied

1

Description of health condition studied

In the present study, in vivo bioequivalence of Azithromycin 250 mg capsules (Ani Darman Co.) compared to Zithromax®

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

City
Tabriz

Province
East Azarbaijan

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
Parviz Shahabi

Street address
No.2 Central Building 3rd Floor, University of Medical Sciences, Daneshgah st.

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

Email
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
Ani Darman 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, University of Medical Sciences, Golgasht st., Attar Neishaboori st.

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

Email
pzakeri@tbzmed.ac.ir

Person responsible for scientific 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.

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

Fax

Email
pzakeri@tbzmed.ac.ir

Person responsible for updating data

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.

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Phone
+98 41 3334 8801

Email
pzakeri@tbzmed.ac.ir

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