Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative bioequivalence study of Azithromycin 250 mg Capsule of Shafa Pharmed and Zithromax of Pfizer as reference in 24 healthy subjects under fasting

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Azithromycin 250 mg capsule formulation as a test product with Zithromax 250 mg capsule of Pfizer formulation as a reference product and to evaluate the bioequivalence of these two formulations.

Design

Non-blinded, randomized, crossover in vivo bioequivalence study in 24 healthy males under fasting conditions. Block randomization for a treatment sequence of Test/Reference or Reference/Test is used

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Noor Research and Development Institute (Tarasht, Tehran). 2 dosing periods will be separated by a 14-day washout period.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthy subjects (male) between 18–55 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Exclusion Criteria: Subjects with known allergy to the products tested. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period.

Intervention groups

Intervention group 1: Azithromycin 250 mg capsule, produced by Shafa Pharmed Co. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: Zithromax 250 mg capsule, produced by Pfizer is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N108**
Registration date: **2026-10-17, 1405/07/25**
Registration timing: **prospective**

Last update: **2026-10-17, 1405/07/25**
Update count: **0**

Registration date

2026-10-17, 1405/07/25

Registrant information

Name
Behzad Montaha Sangari
Name of organization / entity
Noor research and educational institute (Tavan)
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Iran (Islamic Republic of)
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Email address
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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2027-01-08, 1405/10/18

Expected recruitment end date

2027-01-15, 1405/10/25

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of Azithromycin 250 mg Capsule of Shafa Pharmed and Zithromax of Pfizer as reference in 24 healthy subjects under fasting

Public title
Comparative in vivo evaluation of 2 formulations of Azithromycin 250 mg Capsule
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy subjects (male) between 18– 55 years of age. Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m2 Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects with normal vital signs Subjects who agree with patient consent form.
Exclusion criteria:
Subjects with known allergy to the products tested. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Subjects who has used any prescription or OTC drugs 14 days prior to the initiation of study and unable to refrain from the concomitant medications. History of alcohol or drug abuse. Heavy drinker of caffeine, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity. A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study.
Age
From **18 years** old to **55 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
The randomization schedule will be generated with https://www.sealedenvelope.com/simple-randomiser/v1/lists. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer numbers (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of Test/Reference or Reference/Test will be given to each volunteer.
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
Research Ethics Committee of the Faculties of Pharmacy, Nursing and Midwifery – Shahid Beheshti Univ
Street address
Shafa Pharmed Industrial Group Co., Barakat Pharmaceutical Industrial Town, Barakat Street, Kordan, 10th Kilometer of the Karaj–Qazvin Freeway, Iran
City
Tehran
Province
Tehran
Postal code
1996835113
Approval date
2026-09-17, 1405/06/26
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1405.166

Health conditions studied

1

Description of health condition studied
Long term (current) use of antibiotics
ICD-10 code
Z79.2
ICD-10 code description
Long term (current) use of antibiotics

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)
Timepoint
0, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 11, 24, 48, 72 after administration
Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)
Timepoint
0, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 11, 24, 48, 72 after administration
Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Intervention groups

1

Description
Intervention group: One Azithromycin 250 mg Capsule , produced by Shafa Pharmed. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 14-day wash-out period the intervention 2 will be given to these subjects.
Category
Treatment - Drugs

2

Description
Intervention group: One Zithromax 250 mg capsule, produced by Pfizer is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 14-day wash-out period the intervention 1 will be given to these subjects.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Noor Research & Development Institute (Tavan)
Full name of responsible person
Behzad Montaha Sangari
Street address
Sharif Innovation Station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shifa Pharmed Co.
Full name of responsible person
Dr. Saeideh Jalilian
Street address
Shafa Pharmed Industrial Group Co., Barakat Pharmaceutical Industrial Town, Barakat Street, Kordan, 10th Kilometer of the Karaj–Qazvin Freeway, Iran
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3365166451
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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
Shifa Pharmed 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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Noor Research & Development Institute
Full name of responsible person
Behzad Montaha Sangari
Position
CEO(Chef Executive officer)
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Tavan Institute

Full name of responsible person
Seyed Mohsen Foroutan

Position
Principal investigator

Latest degree
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Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity
Noor research and educational institute (Tavan)

Full name of responsible person
Behzad Montah Sangari

Position
CEO(Chef executive officer)

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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Tehran

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
It's undetermind yet.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available