

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparative bioequivalence study of Azithromycin 250 mg Tablet of Cosar Pharmaceutical Co. and Zithromax® of Pfizer as reference in 24 healthy male under fasting condition

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and in vivo parameters of Azithromycin 250 mg Tablet formulation as a test product with Zithromax 250 mg Tablet 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 male under fasting condition.

Settings and conduct

In each period, volunteers will receive a single dose intervention (1 or 2) in the Noor Research & Educational Institute (Tarasht, Tehran). 17 blood samples were collected during 72 hours post intervention. A 7-day washout interval separated to study periods.

Participants/Inclusion and exclusion criteria

Healthy subjects (male) between 20 - 45 years of age and Body Mass Index (BMI) within 15% of normal range between 18.5 - 30 kg/m². Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects with known allergy to the products tested

Intervention groups

Intervention group 1: Azithromycin 250 mg tablet, produced by Cosar pharmaceutical 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 tablet, produced by Roche 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: **IRCT20180620040164N48**

Registration date: **2023-08-19, 1402/05/28**

Registration timing: **prospective**

Last update: **2023-08-19, 1402/05/28**

Update count: **0**

Registration date

2023-08-19, 1402/05/28

Registrant information

Name

Behzad Montaha Sangari

Name of organization / entity

Noor research and educational institute (Tavan)

Country

Iran (Islamic Republic of)

Phone

+98 21 6600 7026

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-13, 1402/07/21

Expected recruitment end date

2023-10-27, 1402/08/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of Azithromycin 250 mg Tablet of Cosar Pharmaceutical Co. and Zithromax® of Pfizer as reference in 24 healthy male under fasting condition

Public title

Comparative in vivo evaluation of 2 Azithromycin 250 mg Tablet and Zithromax 250 Tablet formulations.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range between 18.5 - 30 kg/m². Subjects that have normal vital signs. Subjects who agree with patient consent form.

Exclusion criteria:

Known sensitivity to the tested products, hypertension (blood pressure in the standing position after at least 5 minutes of rest, systolic blood pressure greater than or equal to 140 mmHg, and diastolic blood pressure greater than or equal to 90 mmHg). Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. loss of more than 500 milliliters of blood in less than 7 days prior to testing. Subjects with significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations.

Age

From **20 years** old to **45 years** old

Gender

Male

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/lits>. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer's number (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. so it reveals that each volunteer take the medicine in RT or TR order.

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

Ethics Committee, School of Pharmacy, Nursing & Midwifery; Shahid Beheshti University of medical science

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2023-06-20, 1402/03/30

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.068

Health conditions studied

1

Description of health condition studied

Acute pharyngitis

ICD-10 code

J02

ICD-10 code description

Acute pharyngitis

Primary outcomes

1

Description

Peak Plasma Concentration (C_{max})

Timepoint

17 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 11, 24, 48 and 72 hours after intervention.

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

17 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 11, 24, 48 and 72 hours after intervention.

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 1: Azithromycin 250 mg Tablet, produced by Cosar Pharmaceutical Co. 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 2: Azithromycin 250 mg Tablet (Zithromax®), 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 Institut(Tavan)

Full name of responsible person

Ali aghaei

Street address

Sharif innovation station, North Habibollah Street, Hosseini Square, Teymourey Street, Tarasht.

City

Tehran

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1459926609

Phone

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Email

info@tavaninstitute.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Cosar Pharmaceutical Co.

Full name of responsible person

Dr. Babak Mesbahi

Street address

Darougar street, 17km Old Way Karaj-Tehran.

City

Tehran

Province

Tehran

Postal code

1415519871

Phone

+98 21 4492 1074

Email

info@cosarpharm.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Cosar Pharmaceutical 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

Ali Aghaei

Position

Master

Latest degree

Master

Other areas of specialty/work

Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tavan Institute

Full name of responsible person

Seyed Mohsen Foroutan

Position

Principal investigator

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Latest degree

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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 undetermined yet.

Study Protocol

Undecided - It is not yet known if there will be 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