

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Bioequivalence evaluation of Azithromycin Tablet 100 mg of Mahban Pharmaceutical company

Protocol summary

Study aim

Bioequivalence study of Azithromycin manufactured by Mahban pharmaceutical company

Design

Clinical trials of 24 volunteers

Settings and conduct

After selecting the volunteers, Azithromycin drug manufactured by Mahban and Pfizer will be prescribed to them orally in two doses with an interval of 7 days. For example, if in the first period, the volunteer received the drug manufactured by Mahban, in the next turn, the volunteer will receive the drug manufactured by Pfizer. Each time the amount of 6 cc of blood before drug administration and at times of 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 12, 24, 48, 72 hour after the medication is prescribed. Samples were collected in Anticoagulant tube collection tubes. The tubes were centrifuged and plasma samples were stored at -80 °C. Finally, the amount of drug in each sample is determined by Lc Mass Mass equipment.

Participants/Inclusion and exclusion criteria

Healthy volunteers, no history of diseases affecting the pharmacokinetic processes of the drug, no chronic or acute use of any drug at least 1 week before starting the study

Intervention groups

Volunteers will be divided into two groups: On the first week, group one will receive Azithromycin manufactured by Mahban pharmaceutical company and group number two will receive Azithromycin manufactured by Pfizer pharmaceutical company. On the second week, group number one will receive Azithromycin manufactured by Pfizer pharmaceutical company and group number two will receive Azithromycin manufactured by Mahban pharmaceutical company (cross over)

Main outcome variables

Maximum plasma concentration; area under the curve; the time taken to reach maximum plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200625047913N10**

Registration date: **2024-02-04, 1402/11/15**

Registration timing: **prospective**

Last update: **2024-02-04, 1402/11/15**

Update count: **0**

Registration date

2024-02-04, 1402/11/15

Registrant information

Name

Tayebeh Ghari

Name of organization / entity

Hezareh Sevom Futuristic Pharmacist Company

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 2343

Email address

info@hezareh-co.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-03-04, 1402/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence evaluation of Azithromycin Tablet 100 mg of Mahban Pharmaceutical company

Public title

Bioequivalence evaluation of Azithromycin Tablet 100 mg of Mahban Pharmaceutical company

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

18 to 45 years old Sex: Males and/or non-pregnant, non-lactating females BMI: 18.5 to 24.9 weight in kg/(height in meter) Able to communicate effectively with study personnel and willingness to follow the protocol requirements as evidenced by written informed consent A physical examination with no clinically significant finding and laboratory normal tests Do not take any chronic or acute medication for at least 1 week before the start of the study No history of diseases affecting the pharmacokinetic processes of the drug

Exclusion criteria:

History of allergic responses to Azithromycin or other related drugs, or any of its formulation ingredients Have significant diseases (which might compromise the haemopoietic, gastrointestinal, renal, hepatic, cardiovascular, respiratory, central nervous system, diabetes, psychosis or any other body system) or clinically significant abnormal findings during screening History or presence of bronchial asthma Smokers who smoke 10 or more cigarettes per day or 20 or more biddies per day or those who cannot refrain from smoking during the study period History or evidence of drug dependence or of alcoholism or of moderate alcohol use History of difficulty with donating blood or difficulty in accessibility of veins Volunteers who have received a known investigational drug within five elimination half life of the administered drug prior to the initial dose of study drug or who have participated in a clinical drug study or bioequivalence study within 90 days prior to the initial dose of study drug, whichever is greater Found positive in urine test for drugs of abuse done before check-in of period History of difficulty in swallowing, or of any gastrointestinal disease which could affect drug absorption

Age

From **18 years** old to **45 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

A test and reference drug will be administrated to the volunteers in first week and one week after that. Volunteers do not know which medication they are taking each week.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of institute of pharmaceutical science of Tehran University of Medical Sciences

Street address

16 Azar Avenue, Tehran University of Medical Sciences, Faculty of Pharmacy, The Institute of Pharmaceutical Sciences, 2nd floor, Unit 1-219, Tehran- Iran.

City

Tehran

Province

Tehran

Postal code**Approval date**

2024-01-31, 1402/11/11

Ethics committee reference number

IR.TUMS.TIPS.REC.1402.166

Health conditions studied**1****Description of health condition studied**

-

ICD-10 code

-

ICD-10 code description

-

Primary outcomes**1****Description**

Plasma concentration

Timepoint

0, 0.5, 1, 5/1, 2, 5/2, 3, 5/3, 4, 5, 6, 8, 12, 24, 48, 72 hr

Method of measurement

LC MS MS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Azithromycin 500 mg tablets made by Mahban pharmaceutical company from Iran will prescribe in the first week at fast condition and blood samples will draw in determined intervals.

Category

N/A

2

Description

Control group: Intervention group: Azithromycin 500 mg tablets made by Pfozer pharmaceutical company from Germany will prescribe in the first week at fast condition and blood samples will draw in determined intervals.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hezareh Sevom Futuristic Pharmacist Company

Full name of responsible person

Tayebeh Ghari

Street address

Unit 4, No. 81, Babak Bahrami st, After Zafar st, Tehran, Iran.

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Postal code

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Fax

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Email

info@hezareh-co.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hezareh Sevom Futuristic Pharmacist

Full name of responsible person

Tayebeh Ghari

Street address

Unit 4, No 81, Babak Bahrami st, After Zafar st, Tehran, Iran.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hezareh Sevom Futuristic Pharmacist

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Alborze University of Medical Sciences, School of Pharmacy

Full name of responsible person

Faranak Salmannejad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Alborze School of pharmacy, near Bahonar Hospital, Vali-e-asr st, Shora Blv, Karaj.

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Province

Alborz

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Phone

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Email

salmannejad.f@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Alborze University of Medical Sciences, School of Pharmacy

Full name of responsible person

Faranak Salmannejad

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Alborze University of Medical Sciences, School of
Pharmacy

Full name of responsible person

Faranak Salmannejad

Position

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

All data is potentially shareable after unidentified
individuals.

When the data will become available and for how long

from 2024

To whom data/document is available

People working in industry and academia

Under which criteria data/document could be used

People working in industry and academia

From where data/document is obtainable

Sending email to info@hezareh-co.com - Sending fax to
00982188208678 - Calling to 00982188652343 -

Responsible person: Tayebeh Ghari

What processes are involved for a request to access data/document

Sending email to info@hezareh-co.com/ request
evaluation/sending data

Comments