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 ،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 ℃ . Finally, the amount of drug in each sample is determined by Lc Mass Mass equipment. 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 divided in 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 take 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)

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+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 haemopoeitic, 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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1968655815
Phone
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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
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Other areas of specialty/work
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Person responsible for updating data

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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