Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Bioequivalence evaluation of Azithromycin Capsule 500 mg/ Suspension 200 mg/5 ml manufactured by Dora Darou company

Protocol summary

Study aim

Bioequivalence study of Azithromycin 500 mg Capsule/200mg/5 ml suspension manufactured by Dorsa Darou

Design

Clinical trials of single blind design of 24 volunteers with controlled group.

Settings and conduct

After selecting the volunteers, Azithromycin drug manufactured by Dorsa Darou Company from Iran and Pfizer from Germany will be prescribed to them orally in two doses with an interval of 7 days. For example, if in the first period of the drug administration, the volunteer received the drug manufactured by Dorsa Darou, in the next turn, the volunteer will receive drug manufacturd by Pfizer company . Each time the amount of 6 cc of blood will be taken 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. The next sampling will 7 days later. In the second time, similar to the first time of drug administration, blood sampling will be done. 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 divided in two groups: On the first week, group one will receive Azithromycin manufactured by Dorsa Darou company and group number two will receive Azithromycin manufactured by Pfizer company . On the second week, group number one will receive Azithromycin manufactured by Pfizer company and group number two will receive Azithromycin manufactured by Dorsa Darou 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

BACS (Bioequivalence Azithromycin)capsule suspension

IRCT registration information

IRCT registration number: **IRCT20200625047913N3**
Registration date: **2020-12-11, 1399/09/21**
Registration timing: **prospective**

Last update: **2020-12-11, 1399/09/21**
Update count: **0**

Registration date

2020-12-11, 1399/09/21

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

2021-01-20, 1399/11/01

Expected recruitment end date

2021-02-03, 1399/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence evaluation of Azithromycin Capsule 500 mg/ Suspension 200 mg/5 ml manufactured by Dora Darou company

Public title

Bioequivalence evaluation of Azithromycin Capsule 500 mg/ Suspension 200 mg/5 ml manufactured by Dora Darou 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 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

- Participant

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding 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.

Placebo

Not used

Assignment

Crossover

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

تهران

Province

Tehran

Postal code

۱۴۱۷۶۱۴۴۱۱

Approval date

2020-12-05, 1399/09/15

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.851

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, 1.5, 2, 2.5, 3,3.5,4,5,6,8,12,24,48,72 hour

Method of measurement

LC MS MS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Prescription of Azithromycin 500 mg capsule/200mg/5ml suspension manufactured by Dorsa Darou company from Iran in the first week
Category
Other

2

Description
Control group: Prescription of Azithromycin 500 mg capsule/200mg/5ml suspension manufactured by Pfizer company from Germany in the second week
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hezareh Sevom Futuristic Pharmacist Company
Full name of responsible person
طیبه قاری
Street address
Unit 4, No. 81, Babak Bahrami st, After Zafar st, Tehran, Iran
City
تهران
Province
Tehran
Postal code
1968655815
Phone
+98 21 8865 2343
Email
tayebehghari@gmail.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.
City
Tehran
Province
Tehran
Postal code
1968655815
Phone
+98 21 8865 2343
Email
info@hezareh-co.com
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.
City
Karaj
Province
Alborz
Postal code
3154686689
Phone
+98 26 3256 7175
Fax
+98 26 3256 7176
Email
salmannejad.f@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Alborze University of Medical Sciencesو 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.
City
Karaj
Province
Alborz
Postal code
3154686689
Phone
+98 26 3256 7175
Email
salmannejad.f@gmail.com

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
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.
City
Karaj
Province
Alborz
Postal code
3154686689
Phone
+98 26 3256 7175
Email
salmannejad.f@gmail.com

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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is 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 2021
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