Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Bioequivalence study of 100 mg doxycycline delayed-release capsules manufactured by Behshad Daroo company with reference product manufactured by Avet (Heritage)

Protocol summary

Study aim

The bioequivalence of Behshad Darou's 100 mg delayed-release Doxycycline capsule is being assessed in comparison to the reference product made by Avet (Heritage) company.

Design

This study is conducted as a crossover study during 2 days with a 2 week washout period.

Settings and conduct

After administration of drug fasting condition, blood sampling is performed from the time of administration to 72 hours after drug administration, according to the schedule provided. Blood samples are transferred to heparinized tubes and stored in ice until centrifuged. The resulting plasma is stored at -80 ° C until analysis.

Participants/Inclusion and exclusion criteria

healthy Volunteers, 18-40 years, Body mass index of 18.5-30 kg/cm3 No history of allergy to tetracycline antibiotics and excipients used in the products formulations No history of diseases affecting the pharmacokinetic processes of the drug No administration of potent cytochrome p450 inhibitors 4 weeks before start of the study No history of smoking, alcohol and narcotics use Not being pregnant or breastfeeding Adherence to study criteria based on ethical commitment and informed consent Absence of severe liver failure (Child Pugh B or C) or kidney failure (GFR<30 mL/min/1.73 m2)

Intervention groups

The first group will receive 2 capsules of the reference brand medication in the first period of the study and 2 capsules of the Iranian generic medication in the second period. The second group will receive 2 capsules of the Iranian generic medication in the first period and 2 capsules of the reference brand medication in the second period.

Main outcome variables

Cmax-tmax-AUC0-t

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230629058615N1**
Registration date: **2023-09-24, 1402/07/02**
Registration timing: **prospective**

Last update: **2023-09-24, 1402/07/02**
Update count: **0**

Registration date

2023-09-24, 1402/07/02

Registrant information

Name

Amir Rezazadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 729 8761

Email address

rezazadeh.am@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2023-10-12, 1402/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Bioequivalence study of 100 mg doxycycline delayed-release capsules manufactured by Behshad Daroo company with reference product manufactured by Avet (Heritage)

Public title
bioequivalence study
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Volunteer’s health (based on the results of physical examinations and clinical tests) Volunteer’s health (based on the results of physical examinations and clinical tests) Body mass index of 18.5-30 kg/m2 No history of allergy to tetracycline antibiotics and excipients used in the products formulations No administration of potent cytochrome p450 inhibitors 4 weeks before start of the study No history of diseases affecting the pharmacokinetic processes of the drug No history of smoking, alcohol and narcotics use Not being pregnant or breastfeeding Adherence to study criteria based on ethical commitment and informed consent Absence of severe liver failure (Child Pugh B or C) or kidney failure (GFR<30 mL/min/1.73 m2)
Exclusion criteria:
Pregnancy Tobacco or alcohol use, acute or chronic Failure to obtain any of the mentioned items regarding health tests Drug administration before and during the study Lack of adherence to study criteria Incidence of adverse reactions liver failure (Child Pugh B or C) or kidney failure (GFR<30 mL/min/1.73 m2)
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 24 volunteers will be divided into two groups. The first group will receive the brand medication, and the second group will receive the generic medication. The Grouping will be done in a randomized manner: In this study, 24 medication, including 12 generic medication and 12 brand medication, will be randomly assigned to patients using a random code (including numbers and letters). After coding the drugs, each code will be randomly assigned to an individual using a random command. Due to the crossover design of the study, in the second period, each patient will receive the other type of drug.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, patients will not be informed about the type of drug they are receiving.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Faculty of pharmacy and pharmaceutical sciences, Tehran Medical Sciences, Islami
Street address
Islamic Azad University of Medical Sciences, Shariati St, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1916893813
Approval date
2022-03-10, 1400/12/19
Ethics committee reference number
IR.IAU.PS.REC.1399.238

Health conditions studied

1

Description of health condition studied
The study will be performed on healthy volunteers.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
C max- Tmax- AUC0-t
Timepoint
0 - 0.5 - 1 -1.5 - 2 - 2.5 - 3 - 3.5 - 4 -4.5 - 6 - 8 - 10 to 12 - 24 -48 -72 Hours after drug administration
Method of measurement
Drug analysis will be performed using a high-performance liquid chromatography (HPLC) equipped with a UV detector

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving Iranian generic medicine in the first week and receiving brand medicine in the second week
Category
Other

2

Description
Intervention group: receiving the brand medication in the first week and Iranian generic medication in the second week
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Farhikhtegan hospital
Full name of responsible person
Hamidreza Gholamrezaei
Street address
Tehran Province, Tehran, Hesarak, Shohadaye Hesarak Blvd
City
tehran
Province
Tehran
Postal code
1477899679
Phone
+98 21 4486 7262
Fax
+98 21 4484 5171
Email
farhikhteganhospital@gmail.com
Web page address
http://farhikhtegan.iautmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Behshad Daroo Company
Full name of responsible person
Alireza Khalkhali
Street address
No 36, East Sepand St, Nejatollahi St., Karimkhan Zand Blvd., Tehran-Iran
City
tehran
Province
Tehran
Postal code
1898993733
Phone
+98 21 8880 2889
Fax
+98 21 8890 8704
Email
info@behshadpharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Behshad Daroo Company
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
Islamic Azad University
Full name of responsible person
Farshad Hashemian
Position
faculty member
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Tehran, Gholhak, Dr. Shariati St., Yakhchal St., School of Pharmacy.
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tehran
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1941933111
Phone
22640599
Email
fhashemian@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Amir

Position
assistant professor

Latest degree
Specialist

Other areas of specialty/work
Clinical Pharmacy

Street address
Shahid Hemet highway , Shahid Kabiri Tameh St. (Shahin North) at the end of Shahid Basarati St., School of Pharmacy

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Postal code
1475886671

Phone
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Email
rezazadeh.am@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Kamyab Andarzbakhsh

Position
Clinical cooperator of the study

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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Kamyab.dr@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
Blood concentrations of received medication by individuals and the exact protocol of drug administration

When the data will become available and for how long
After publishing the article related to the study

To whom data/document is available
The main person responsible for similar studies

Under which criteria data/document could be used
designing similar studies

From where data/document is obtainable
Islamic Azad university

What processes are involved for a request to access data/document
Application registration in the administrative department of the university

Comments