

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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 Daroo'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

C_{max}-t_{max}-AUC_{0-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- AUC_{0-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

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Phone

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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

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tehran

Province

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Postal code

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Phone

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Fax

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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

Province

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Postal code

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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rezazadeh.am@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Kamyab Andarzbaksh

Position

Clinical cooperater of the study

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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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

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