Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Bioequivalence study of of the Doxycycline Hyclate 100 mg Delayed-Release Capsules manufactured by Behsazan Pazhohan Omid Arya Pharmaceutical Company vs. Doryx ® tablets manufactured by Mayne Pharma Company in healthy volunteer

Protocol summary

Study aim
Examining the bioequivalency of domestically produced Doxycycline capsule formulations with Doryx ® brand

Design
A cross over, unblinded, randomized, bioequivalence clinical trial on 24 healthy volunteers.

Settings and conduct
Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. The number of 24 volunteers in the age range of 18-50 years who are voluntarily selected through public notification. One capsule is taken fasting and blood is taken at 18 time points. A week later, the process is repeated for the brand medicine

Participants/Inclusion and exclusion criteria
The weight range of 60-100 kg; being a non-smoker; being healthy in terms of physical examination, ECG, and the laboratory tests; and Volunteers who have agreed to an informed consent form. Exclusion criteria: History of allergic or adverse reaction to Doxycycline or any similar product; blood pressure less than 90 mm Hg or higher than 140 mm Hg; Individuals who have donated whole blood during the previous 2 months of the study or donated blood components within 2 weeks before taking the first dose of the drug.

Intervention groups
Intervention group 1: the Doxycycline Hyclate 100 mg Delayed- Release capsule manufactured by Behsazan Pazhohan Omid Arya Pharmaceutical Company is the test product. Intervention group 2: Doryx ® Tablets manufactured by Mayne Pharma company is the reference product. In each period, 12 of 24 subjects will be given single dose of this product and for up to 72hours, 3 ml of blood will be collected from the volunteer at 16 time points each time. After one week washout period, the volunteers are placed in the opposite group

Main outcome variables
Plasma concentration of the drug

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130313012810N99**
Registration date: **2026-05-21, 1405/02/31**
Registration timing: **prospective**

Last update: **2026-05-21, 1405/02/31**
Update count: **0**

Registration date
2026-05-21, 1405/02/31

Registrant information

Name
Hamed Hamishehkar
Name of organization / entity
Drug Applied Research Center, Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-28, 1405/03/07

Expected recruitment end date
2026-05-31, 1405/03/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Bioequivalence study of of the Doxycycline Hyclate 100 mg Delayed- Release Capsules manufactured by Behsazan Pazhohan Omid Arya Pharmaceutical Company vs. Doryx ® tablets manufactured by Mayne Pharma Company in healthy volunteer

Public title
Doxycycline capsule bioequivalence
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The weight range of participating candidates should be between 60-100 kg All candidates must be non-smokers. Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form. All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw.
Exclusion criteria:
History of allergic or adverse reaction to Doxycycline or any similar product Volunteers with blood pressure less than 90 mm Hg or higher than 140 mm Hg Individuals who have donated whole blood during the last 2 months from the study Individuals who have donated blood components within 2 weeks before taking the first dose of the drug.
Age
From **18 years** old to **50 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
To randomly assign people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes arranged irregularly. Each candidate will pick up an envelope after entering the study, and numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1, and group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Daneshgah Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5165665811
Approval date
2026-04-27, 1405/02/07
Ethics committee reference number
IR.TBZMED.REC.1405.073

Health conditions studied

1

Description of health condition studied
Bioequivalence study in healthy volunteers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of the drug
Timepoint
16 sampling time included pre-dose (time 0) and at the following hours post-dose: 0.5، 1، 1.5، 2، 2.5، 3، 3.5، 4، 5، 6، 8 ، 12، 24، 48 and 72h
Method of measurement
Liquid Chromatography with tandem mass spectrometry

(LC-MS-MS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, volunteers are given a single oral dose of Doxycycline Hyclate 100 mg Delayed- Release capsule manufactured by Behsazan Pazhohan Omid Arya Pharmaceutical Company. In each period, 12 of 24 subjects will be given a single oral dose of this product. After one week washout period, the volunteers are placed in the Intervention group 2.
Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, volunteers are given a single oral dose ofthe Doxycycline Hyclate 100 mg Delayed- Release, capsule manufactured by Mayne Pharma Company. In each period, 12 of 24 subjects will be given a single oral dose of this product. After one week washout period, the volunteers are placed in the Intervention group 1.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Drug Applied Research Center, Tabriz University of Medical Sciences
Full name of responsible person
Hamed Hamishehkar
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Drug Applied Research Center, Tabriz University of Medical Sciences,Daneshghah St., Tabriz,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zist takhmir company
Full name of responsible person
Said Hemmati
Street address
No. 597, Heydarkhani 4 way, Farjam Street, Resalat Square
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Tehran
Postal code
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Email
info@zisttakhmir.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zist takhmir 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
Tabriz University of Medical Sciences
Full name of responsible person
Hamed Hamishehkar
Position
Professor
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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