Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative bioequivalence Study of the Eltrombopag 50 mg Tablets, Manufactured by Arang Daroo Darman Pharmaceutical Company by Innovative Company (Revolade)

Protocol summary

Study aim

Comparison Bioequivalence study of Eltrombopag 50 mg tablets produce by Daroo Darman Arang Pharmaceutical Company and Its the brand Product

Design

This study is a single-blind crossover study with two intervention groups of 12, randomized by the Rand function of SPSS software. The sample size is 24, randomly selected and randomly divided into two groups.

Settings and conduct

In this study, which will be conducted at the Tabriz Bioassay Drug Monitoring Laboratory, there are two intervention groups that have been randomized using the Rand function of SPSS software. The first and second groups will take the Iranian and brand-name drugs, respectively, without knowing it, and blood will be drawn at specific intervals. Since it is one-sided, this procedure will be repeated after a washout period and the equivalence of the drugs will be examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: General health (liver, heart, and kidney) Body mass index between 18 and 28) Informed consent Age between 18-60 years Exclusion criteria: Smoking History of cardiovascular disease Pregnancy Alcohol and drug addiction History of allergy to this drug

Intervention groups

In this study, there are two intervention groups, the first and second groups taking Iranian and branded drugs, respectively. After a cleansing period, this process is reversed and the equivalence of the drugs is examined based on blood concentrations taken at specific times.

Main outcome variables

Drug Concentration

General information

Reason for update

Acronym

None

IRCT registration information

IRCT registration number: **IRCT20231108059993N8**
Registration date: **2025-10-23, 1404/08/01**
Registration timing: **prospective**

Last update: **2025-10-23, 1404/08/01**
Update count: **0**

Registration date

2025-10-23, 1404/08/01

Registrant information

Name

Iran Ghanbarzadeh

Name of organization / entity

Alborz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 41 3383 2649

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s_ghanbarzadeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-05, 1404/08/14

Expected recruitment end date

2025-11-19, 1404/08/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative bioequivalence Study of the Eltrombopag 50 mg Tablets, Manufactured by Arang Daroo Darman Pharmaceutical Company by Innovative Company (Revolade)

Public title
Comparative bioequivalence study of the Eltrombopag 50 mg Tablets, Manufactured by Daroo Darman Arang Pharmaceutical Company

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
Must be in good general health (liver, heart, and kidneys). Body mass index should be in the range of 18-28. Informed consent must be obtained. Age must be between 18-60 years.

Exclusion criteria:
History of allergic or adverse reaction to eltrombopag or any similar product. Addiction to cigarettes, alcohol, or any type of drug Volunteers with a history of chronic diseases such as high blood pressure or high blood lipids, etc. who have taken medication in the past two months.

Age
From **18 years** old to **60 years** old

Gender
Male

Phase
Bioequivalence

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals in the age group mentioned are invited to participate through an advertisement. Then, individuals are checked for health and healthy volunteers are identified. Each volunteer is assigned a number from 1 to 24. The numbers are written on a plastic ball and poured into a container and mixed. Then, balls are randomly removed from the container. The first 12 people are considered as (sequence one: recipients of elentrombopag 50) and the second 12 people are considered as (sequence two: recipients of rovalipin 50). The participating volunteers are unaware of receiving the test drug or the brand drug.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a single-blind (participant) clinical trial. Eltrombopag tablets are removed from their packaging by the investigator and placed in identical, coded containers. Volunteers are unaware of the type of drug they are taking in each series of the experiment.

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
Drug Applied Research Center, Tabriz University of Medical Sciences Daneshgah St. Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5167698354184

Approval date
2025-10-06, 1404/07/14

Ethics committee reference number
IR.TBZMED.REC.1404.526

Health conditions studied

1

Description of health condition studied
Healthy volunteer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
At specific intervals, the blood concentration of the drug is measured and compared in two series of blood draws, and it is determined whether the drugs are equivalent or not.

Timepoint
Drug concentrations are measured at time intervals of 0, 0.5, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 24, 48, and 72 hours after drug administration.

Method of measurement
Liquid chromatography with dual mass spectrometer LC/MS/MS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 receives an Iranian drug and blood concentrations are obtained at specific time intervals. In the second series, this group receives the brand name drug.
Category
Other

2

Description
The intervention group receives 2 brand drugs and blood concentrations are obtained at specific intervals. In the second series, this group receives the Iranian drug. Finally, the results obtained from the two intervention groups are compared and it is determined whether they are equivalent or not.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Payesh Daroo Zist Azma
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arang Daroo Darman
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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
Arang Daroo Darman
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
Phayesh Daroo Zist Azma
Full name of responsible person
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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
None

When the data will become available and for how long
None

To whom data/document is available
None

Under which criteria data/document could be used
None

From where data/document is obtainable
None

What processes are involved for a request to access data/document
None

Comments