Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative Bioequivalence Study of the Eltrombopag 50 mg Tablet Manufactured by Actero Middle East Pharmaceutical Company by Innovative Company

Protocol summary

Study aim

Comparative Bioequivalence Study of the Eltrombopag 50 mg Tablet Manufactured by Actero Middle East Pharmaceutical Company by Innovative Company

Design

This is a double-blind, randomized, crossover clinical trial. (Using the rand function of Excel software). The bioequivalence phase will be conducted on 24 healthy volunteers. In this study, there are two intervention groups, each with 12 volunteers. The first group will take the Iranian drug and the second group will take the brand drug. After a 2-week washout period, the first group will take the brand drug and the second group will take the Iranian drug. Each person is their own control sample, and the results of each person in each round of the experiment will be compared with their own results in the second round of the experiment.

Settings and conduct

Volunteers from the city of Tabriz were randomly selected and after ensuring their health, the volunteers were randomly and double-blindly divided into two intervention groups. The first group will receive the Iranian drug and the second group will receive the brand drug. After 2 weeks, the first and second groups will receive the brand or Iranian drug, respectively, in a crossover manner. In such a way that no one except the experimenter will know the type of drug they will take.

Participants/Inclusion and exclusion criteria

General health (liver, heart and kidneys). Body mass index (18-28). Informed consent. Volunteers age (18-60 years). Sensitivity to Company

Intervention groups

Volunteers will be randomly divided into two intervention groups and will take one Eltrombopag 50 mg Tablet of Iranian-made and brand, respectively. According to the protocol, blood will be drawn at different times (16 points), and after a 2-week washout period, they will take the branded and Iranian drug in a cross-over manner.

Main outcome variables

Drug Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231108059993N9**
Registration date: **2025-11-18, 1404/08/27**
Registration timing: **prospective**

Last update: **2025-11-18, 1404/08/27**
Update count: **0**

Registration date

2025-11-18, 1404/08/27

Registrant information

Name

Iran Ghanbarzadeh

Name of organization / entity

Alborz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 41 3383 2649

Email address

s_ghanbarzadeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-16, 1404/08/25

Expected recruitment end date

2025-11-21, 1404/08/30

Actual recruitment start date

2025-11-26, 1404/09/05

Actual recruitment end date

2025-11-27, 1404/09/06

Trial completion date

2025-12-21, 1404/09/30

Scientific title

Comparative Bioequivalence Study of the Eltrombopag 50 mg Tablet Manufactured by Actero Middle East Pharmaceutical Company by Innovative Company

Public title

Comparative bioequivalence study of the Eltrombopag 50 mg Tablet Manufactured by Actero Middle East Pharmaceutical Company

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Good general health (liver, heart, and kidneys) Body mass index (18-28) Informed consent Age (18-60 years)

Exclusion criteria:

Addiction to alcohol, drugs and cigarettes Sensitivity to Eltrombopag Chronic disease treatment history

Age

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

Gender

Male

Phase

Bioequivalence

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **24**

Actual sample size reached: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomly assign individuals to two groups, 24 cards numbered 1 to 24 in sealed envelopes placed in random order will be used. Each volunteer will pick an envelope after entering the study, and those who picked numbers 1-12 will be placed in group A and those who picked numbers 13-24 will be placed in group B. Volunteers in group A will receive the Iranian drug and volunteers in group B will receive the brand drug, and blood will be drawn at specific intervals according to a specific protocol. After a 2-week cleansing period, cross-over, those who have taken the Iranian drug will take the Brand drug and those who have taken the foreign drug will take the Iranian drug, and blood will be drawn again at different intervals. The blood draw results of each person in the second series of blood draws will be compared with their own blood draw results in the first round.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind clinical trial. Eltrombopag 50 mg tablets are removed from their packaging by the investigator and placed in identical, coded containers. Except for the principal investigator, neither the patient, the physician, nor other medical personnel, nor even those performing the concentration analysis, know which patient took which drug in the first or second round

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

Golgasht Ave., Tabriz University of Medical Sciences, Central Building No. 2, Third Floor, Vice President for Research and Technology، Tabriz University of Medical Sciences, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5186733664

Approval date

2025-11-03, 1404/08/12

Ethics committee reference number

IR.TBZMED.REC.1404.579

Health conditions studied

1

Description of health condition studied

Healthy volunteers were enrolled in the study

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug Plasma Concentration

Timepoint

0, 0.5, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 24, 48, 72

Method of measurement

Liquid chromatography with dual mass spectrometer (LC/MŚ/MS)

Secondary outcomes

1

Description
Drug Plasma Concentration
Timepoint
0, 0.5, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 24, 48, 72
Method of measurement
Liquid chromatography with dual mass spectrometer (LC/MŜ/MS)

2

Description
Drug Plasma Concentration
Timepoint
0, 0.5, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 24, 48, 72
Method of measurement
Liquid chromatography with dual mass spectrometer (LC/MŜ/MS)

Intervention groups

1

Description
Intervention group: Intervention group: The first intervention group, which has been randomly and double-blindly selected, will take the Iranian Eltrombopag 50 mg tablets, and the second group will take a brand drug . After a 2-week washout period, the first group will take the brand-name drug and the second group will take the Iranian drug, and blood will be taken from them at 17 time points.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Payesh Darou Zist Azma
Full name of responsible person
Saeed Ghanbarzadeh
Street address
No. 10, Olympic Building, Mehrab Ave., Mirdamad Ave., Tabriz
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5166934184
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Email
s_ghanbarzadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Actero Middle East Pharmaceutical Company
Full name of responsible person
Meysam mohammadnejhad
Street address
No. 145, Ronicaplus Building, 4th Floor, East Shahid Majid Gharavi Street, Shahid Ayatollah Ashrafi Esfahani Highway, South Ponak, Tehran
City
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Tehran
Postal code
۱۴۷۶۷۸۵۵۳۴
Phone
+98 21 4434 8411
Email
info@acteropharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Actero Middle East Pharmaceutical 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
Saeed Ghanbarzadeh
Position
Associate Professor
Latest degree
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Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable