Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 2026

Bioequivalence study of mesalazine 1200 mg extended-release tablets - Actoveerco Pharmaceutical Company

Protocol summary

Study aim
Bioequivalence study of mesalazine 1200 mg extended-release tablets - Actoveerco Pharmaceutical Company

Design
Bioequivalence study, Cross-over design, Single dose, Single-blinded, 24 healthy volunteers, Two period, one week wash out period, Simple randomization method will be used.

Settings and conduct
This single-blind, two-period crossover study was conducted on two groups of healthy volunteers at Radin Shimi Company in Tabriz. Each period lasted 72hours, with a one-week washout interval between them. In the first period, based on computer-generated randomization, Group 1 received the reference drug while Group 2 received the test drug. In the second period, the treatments were switched. The study was single-blinded, meaning that participants were unaware whether they received the test or reference drug during either sampling period.

Participants/Inclusion and exclusion criteria
No history of heart, kidney & liver disease. The ages and BMIs of participant should be in the range of 18-55 and 18-30 respectively. Exclusion criteria: Smoking, Alcohol and drug addiction, History of allergy to drug, Pregnancy.

Intervention groups
Intervention group one receives mesalazine 1200 mg extended-release tablets - Actoveerco in the first round, and in the second round, after a one-week washout period, the drug Mesavant 1200 mg SR tablet, manufactured by Shire pharma. Intervention group No.2 receives the drugs in the switched order.

Main outcome variables
The concentration of the drug in blood, Time to reach maximum blood concentration, Extent of absorption

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240804062647N8**
Registration date: **2025-10-30, 1404/08/08**
Registration timing: **prospective**

Last update: **2025-10-30, 1404/08/08**
Update count: **0**

Registration date
2025-10-30, 1404/08/08

Registrant information

Name
Massoud Amanlou

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6695 9067

Email address
amanlou@tums.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-12-01, 1404/09/10

Expected recruitment end date
2026-12-01, 1405/09/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bioequivalence study of mesalazine 1200 mg extended-release tablets - Actoveerco Pharmaceutical Company

Public title
Bioequivalence study of mesalazine 1200 mg extended-release tablets - Actoveerco Pharmaceutical Company
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General health (liver, heart, kidney) of volunteers Informed consent form Body mass index range (18-30) Age between18-55
Exclusion criteria:
Smoking Having a history of cardiovascular disease Having a history of liver & kidney disease Having a Alcohol & Drug addiction Having a hypersensitivity to the drug Pregnancy
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **40**
Blood sample
Randomization (investigator's opinion)
Randomized
Randomization description
At first, all of the volunteers are evaluated for meeting inclusion criteria, selecting the final participants. Each volunteer is randomly assigned to a number between 1 and 24 using simple randomization, receiving an identification card containing the assigned number. Next, at first study period, volunteers with even numbers will receive the reference drug and volunteers with odd numbers will receive the test drug. In the second period, the formulations are switched in a cross-over design. The formulation assignment to the subjects is done randomly, with the participants and the trial staff not aware the formulation administered, thus, providing the blinding situation for all stages of the study.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a single-blind (participant) clinical trial. mesalazine 1200 mg extended-release tablets - Actoverco Pharmaceutical Company and the original brand are removed from their packaging by the operator and placed in identical, coded cans. Volunteers are unaware of the type of drug or test they are receiving.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences ethics committe
Street address
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street,
City
Tabriz
Province
East Azarbaijan
Postal code
5174864471
Approval date
2025-10-06, 1404/07/14
Ethics committee reference number
IR.TBZMED.REC.1404.533

Health conditions studied

1

Description of health condition studied
This study is performed on healthy volunteers.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The concentration of the drug in blood
Timepoint
0 , 1 , 2 , 3 , 4 , 5 , 6 , 7 , 7.5 , 8 , 8.5 , 9 , 9.5 , 10 , 10.5 , 11 , 12 , 24 , 48 , 72h after drug
Method of measurement
Liquid Chromatography with Mass-Mass Detector

Secondary outcomes

1

Description
Time to reach maximum blood concentration
Timepoint
After intervention
Method of measurement
The time to reach the maximum drug concentration in blood is recorded. This is done after completing the device analysis of the samples and through the WinNonLine software developed by Phoenix Company.

2

Description
Extent of absorption

Timepoint
After intervention
Method of measurement
Calculation of area under curve of concentration -time

Intervention groups

1

Description
Intervention group: Single-dose of mesalazine 1200 mg extended-release tablets - Actoverco , in the first period. Cross-over design with one week wash out period.After one week in the second period, a single dose of Mesavant 1200 mg SR tablet, manufactured by Shire pharma
Category
Treatment - Drugs

2

Description
Intervention group: Single-dose of Mesavant 1200 mg SR tablet, manufactured by Shire pharma , in the first period. Cross-over design with one week wash out period.After one week in the second period, a single dose of mesalazine 1200 mg extended-release tablets - Actoverco
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Radin laboratory
Full name of responsible person
Bahram Ataii
Street address
No.22, first floor, Moalem st., Abureihan St
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Tabriz
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East Azarbaijan
Postal code
5154995671
Phone
+98 914 311 5717
Email
ataii.bahram@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Actoverco Pharmaceutical Company
Full name of responsible person
Reza Karimi Mostofi
Street address
No58,Eighth ST,Nasr Alley,Tehran
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Tehran
Postal code
1998678111
Phone
+98 21 4163 7000
Email
INFO@ACTOVERCO.COM
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Actoverco 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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Massoud Amanlou
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
These data are as secure between researchers and related industries.
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