

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 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 - Actoverco 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 between 18-55

Exclusion criteria:

Smoking
Having a history of cardiovascular disease
Having a history of liver & kidney disease
Having a history of 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 committee

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

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No.22, first floor, Moalem st., Abureihan St

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Actoverco Pharmaceutical Company

Full name of responsible person

Reza Karimi Mostofi

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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

Medical Pharmacy

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inquiries

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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