

# 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  
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

**Street address**

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

**City**

Tabriz

**Province**

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

**City**

Tehran

**Province**

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**

Medical Pharmacy

**Street address**

16 Azar Ave., Faculty of Pharmacy

**City**

Tehran

**Province**

Tehran

**Postal code**

1417614411

**Phone**

+98 21 6695 9067

**Fax**

+98 21 6412 1111

**Email**

amanlou@tums.ac.ir

**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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## **Person responsible for updating data**

### **Contact**

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Tehran University of Medical Sciences

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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