Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Bioequivalence Study of Mirabegron 50 mg Extended Release (ER) Tablet: Comparison of the Test Drug Manufactured by Actoverco Pharmaceutical Company with the Reference Drug, Betmiga 50 mg

Protocol summary

Study aim

A Bioequivalence (BE) study of Mirabeta (Mirabegron) 50 mg Extended Release (ER) tablet manufactured by Actoverco Pharmaceutical Company in comparison with the reference drug Betmiga 50 mg Extended Release (ER) tablet.

Design

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

Settings and conduct

This single-blind, cross-over trial is conducted in two 144-hour periods with a five-week Washout Period (WP) on healthy volunteers at Radin Shimi Company, Tabriz. In the first period, based on computer randomization, one group receives the reference drug and the other receives the test drug; in the second period, this sequence is reversed. Participants are blinded, meaning they remain unaware of whether they receive the test or reference drug during any sampling period.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: No history of cardiac, renal, or hepatic diseases; age between 18 and 55 years; body mass index between 18 and 30. Exclusion Criteria: Smoking; alcohol or substance abuse; history of drug hypersensitivity; pregnancy.

Intervention groups

Participants in this study are divided into two groups; such that Intervention Group 1 receives a single dose of Mirabeta (Mirabegron) 50 mg Extended Release (ER) tablet manufactured by Actoverco Pharmaceutical Company in the first period, and after a five-week Washout Period (WP), receives the reference drug Betmiga 50 mg Extended Release (ER) tablet manufactured by Astellas Pharma in the second period, while Intervention Group 2 receives these medications in the reverse 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: **IRCT20240804062647N39**
Registration date: **2026-06-04, 1405/03/14**
Registration timing: **prospective**

Last update: **2026-06-04, 1405/03/14**
Update count: **0**

Registration date

2026-06-04, 1405/03/14

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

2026-06-20, 1405/03/30

Expected recruitment end date

2027-06-20, 1406/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Bioequivalence Study of Mirabegron 50 mg Extended Release (ER) Tablet: Comparison of the Test Drug Manufactured by Actoverco Pharmaceutical Company with the Reference Drug, Betmiga 50 mg

Public title

Bioequivalence Study of Mirabegron ER tablet

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 Pregnancy Having a hypersensitivity to the drug Having a Alcohol & Drug addiction

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant

Sample size

Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **42**
Blood sample

Randomization (investigator's opinion)

Randomized

Randomization description

First, all candidates are screened based on the inclusion criteria and selected. Each participant is randomly assigned a number between 1 and 24 using Microsoft Excel software. Then, each participant receives an identification card containing the assigned number. In the first phase, participants with even numbers will receive the reference drug, and participants with odd numbers will receive the test drug. In the second phase, the drugs are crossed over. The sequence of drug allocation to the numbers is performed randomly and without the knowledge of the participants and the evaluation team; thus, the blinding of the participants and investigators is maintained at all stages of the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blind (participant) clinical trial. Mirabegron 50 mg ER tablet of The Test Drug manufactured by 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

Vice-Chancellery for Research and Technology, 3rd Floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5174864471

Approval date

2026-05-11, 1405/02/21

Ethics committee reference number

IR.TBZMED.REC.1405.091

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, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 7, 8, 9, 10, 24, 48, 72, 96, 120, and 144 hours after drug administration

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 1: Participants who receive a single dose of Mirabegron 50 mg Extended Release (ER) tablet, manufactured by Actoverco Pharmaceutical Company, in the first period, and after a five-week Washout Period (WP), receive the reference drug, Betmiga 50 mg Extended Release (ER) tablet, in the second period.
Category
Treatment - Drugs

2

Description
Intervention Group 2: Participants who receive a single dose of the reference drug, Betmiga 50 mg Extended Release (ER) tablet manufactured by Astellas Pharma, in the first period, and after a five-week Washout Period, receive a single dose of the test drug, Mirabegron 50 mg Extended Release (ER) tablet, manufactured by Actoverco Pharmaceutical Company, in the second period.
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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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
Academic staff and full-time professor of the Faculty of Pharmacy
Latest degree
Ph.D.
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Medical Pharmacy
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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