Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative bioequivalence study of Mirabegron 50 mg Extended-Release Tablets manufactured by Darou Andishe Novin Shargh Pharmaceutical Co. vs. Betmiga® tablets manufactured by Astellas in healthy volunteers

Protocol summary

Study aim
Examining the bioequivalency of domestically produced Mirabegron 50 mg Extended-Release tablet formulations with brand name Betmiga®

Design
A cross over, not blinded, randomized, bioequivalence clinical trial on 24 healthy volunteers.

Settings and conduct
Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. The number of 24 healthy volunteers in the age range of 18-55 years and the Body Mass Index range of 18-30, who are voluntarily selected through public notification, take 1 extended-release tablet of 50 mg fasting and blood is taken at 14 time points (up to 72 hours). Two weeks later, the process is repeated for the reference medicine.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The weight range of 60-100 kg; being a non-smoker; being healthy in terms of physical examination, ECG, and the laboratory tests; Volunteers who have agreed to an informed consent form. Exclusion criteria: History of allergic or adverse reaction to Mirabegron or any similar product; blood pressure less than 90/60 mm Hg or higher than 140/90 mm Hg; Individuals who have donated whole blood during the previous 2 months of the study or donated blood components within 2 weeks before taking the first dose of the drug.

Intervention groups
Intervention group 1: Mirabegron 50 mg Extended-Release Tablets manufactured by Darou Andishe Novin Shargh Pharmaceutical Co. is the test product. Intervention group 2: Betmiga® tablets manufactured by Astellas is the reference product. In each period, 12 of 24 subjects will be given a single fasting oral dose of this product and for up to 72 hours, blood will be collected from the volunteer at 14 time points. After the washout period (two weeks), the volunteers are placed in the opposite group.

Main outcome variables
Plasma concentration of the drug

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130313012810N157**
Registration date: **2026-10-25, 1405/08/03**
Registration timing: **retrospective**

Last update: **2026-10-25, 1405/08/03**
Update count: **0**

Registration date
2026-10-25, 1405/08/03

Registrant information

Name
Hamed Hamishehkar

Name of organization / entity
Drug Applied Research Center, Tabriz University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-09-30, 1405/07/08
Expected recruitment end date
2026-10-02, 1405/07/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of Mirabegron 50 mg Extended-Release Tablets manufactured by Darou Andishe Novin Shargh Pharmaceutical Co. vs. Betmiga® tablets manufactured by Astellas in healthy volunteers

Public title
Mirabegron extended-release tablet bioequivalence
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The weight range of participating candidates should be between 60-100 kg. All candidates must be non-smokers. Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose. Volunteers who have agreed to an informed consent form. All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw.
Exclusion criteria:
History of allergic or adverse reaction to Mirabegron or any similar product. Volunteers with blood pressure less than 90/60mm Hg or higher than 140/90mm Hg. Individuals who have donated whole blood during the last 2 months. Individuals who have donated blood components, such as platelets, within the past 2 weeks.
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**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomly assign people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes arranged irregularly. Each candidate will pick up an envelope after entering the study, and numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1, and group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period.
Blinding (investigator's opinion)
Not blinded
Blinding description
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
Tabriz University of Medical Sciences, Daneshgah Street, Tabriz
City
Tabriz
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East Azarbaijan
Postal code
5165665811
Approval date
2026-09-07, 1405/06/16
Ethics committee reference number
IR.TBZMED.REC.1405.384

Health conditions studied

1

Description of health condition studied
Bioequivalence study in healthy volunteers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of the drug
Timepoint
14 time points 0, 1, 2, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10, 24, 48 and 72 hours after drug administration
Method of measurement
Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, volunteers are given a single oral dose of Mirabegron 50 mg tablets manufactured by Anousha Pharmaceutical Company. In each period, 12 of 24 subjects will be given a single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 2.
Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, volunteers are given a single oral dose of the Mirabegron 50 mg Extended-Release Tablets manufactured by Astellas. In each period, 12 of 24 subjects will be given a single oral dose of this product. After the washout period (two weeks), the volunteers are placed in the Intervention group 1.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Drug Applied Research Center, Tabriz University of Medical Sciences
Full name of responsible person
Hamed Hamishehkar
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Darou Andisheh Novin Shargh 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
Hamed Hamishehkar
Position
professor
Latest degree
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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
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