Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative bioequivalence study of the Mirabegron 25 mg Extended-Release Tablets manufactured by Anousha Pharmaceutical Company

Protocol summary

Study aim
Examining the bioequivalency of domestically produced Mirabegron tablet formulations with brand one named Betmiga

Design
A single-group, not blinded, not 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 volunteer in the age range of 18-50 years and the Body Mass Index range of 18-30, who are voluntarily selected through public notification. One tablet is taken fasting and blood is taken at 14 time points. Two weeks later, the process is repeated for the brand medicine

Participants/Inclusion and exclusion criteria
Inclusion criteria: the weight range of 60-100 kg; being 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 60/90 mm Hg or higher than 90/140 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: After taking a Mirabegron 25-mg tablet from a domestic company, 3 milliliters of blood will be collected from the volunteer in 14 times intervals during 72 hours. Two weeks later, the process is repeated for the brand tablet. The drug concentration is measured in plasma.

Main outcome variables
Plasma concentration of the drug

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130313012810N72**
Registration date: **2025-12-16, 1404/09/25**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-16, 1404/09/25**
Update count: **0**

Registration date
2025-12-16, 1404/09/25

Registrant information

Name
Hamed Hamishehkar
Name of organization / entity
Drug Applied Research Center, Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 41 1336 3311
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-16, 1404/09/25

Expected recruitment end date
2025-12-21, 1404/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative bioequivalence study of the Mirabegron 25 mg Extended-Release Tablets manufactured by Anousha Pharmaceutical Company

Public title
Bioequivalence Review of Mirabegron Tablets

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 60/90 mm Hg or higher than 90/140 mm Hg Individuals who have donated whole blood during the last 2 months from the study Individuals who have donated donated blood components within 2 weeks before taking the first dose of the drug

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
N/A

Randomization description

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

Province
East Azarbaijan

Postal code
5165665811

Approval date
2025-11-10, 1404/08/19

Ethics committee reference number
IR.TBZMED.REC.1404.591

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 sampling time included pre-dose (time 0) and at the following hours post-dose: 1, 2, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 24, 48, and 72h

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 25 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 Mirabegron 25 mg tablets manufactured by Betmiga 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 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
Name of organization / entity
Anosha pharmaceutical Company
Full name of responsible person
Nazanin Nami Moghaddam
Street address
Tasnim Building, No. 3, 14th East Street, Beyhaghi Street, Argentina Square, Tehran
City
Tehran
Province
Tehran
Postal code
1515667911
Phone
+98 21 8817 4810
Email
info@tasnimpharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Anosha 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
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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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
Industry license will be required

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