Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Bioequivalence study of Mirabegron 50 mg slow-release tablets from Teb Mofid Nikan Pharmaceutical Company compared to Mirabegron 50 mg slow-release tablets from Astellas, UK, on healthy volunteers

Protocol summary

Study aim

Bioequivalence study of Mirabegron 50 mg slow-release tablets from Teb Mofid Nikan Pharmaceutical Company compared to Mirabegron 50 mg slow-release tablets from Astellas, UK, on healthy volunteers

Design

The present clinical trial includes a bioequivalence study of the slow-release mirabegron 50 mg tablet from Teb Mofid Nikan Pharmaceutical Company compared to the slow-release mirabegron 50 mg tablet from Astellas, UK, after administration to 24 healthy human volunteers, in a two-group, crossover, unblinded, and non-randomized manner.

Settings and conduct

The study is conducted at the premises of Nik Azma Pars Alborz Company located in Garmdareh, Karaj. The study is an unblinded crossover study, consisting of two stages (oral administration of one 50 mg Mirabegron slow-release tablet per study session, and a total of 2 sessions) with a two-week washout period on 24 healthy fasting volunteers. Then, the obtained blood samples are quantified.

Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy volunteers; between the ages of 18 and 55; non-smokers. Exclusion criteria: volunteers with blood pressure less than 90 over 60 mm Hg or higher than 140 over 90 mm Hg

Intervention groups

The study consists of two phases: Intervention 1: Oral consumption of Mirabegron 50 mg slow-release tablets from Teb Mofid Nikan Pharmaceutical Company, Iran, and Intervention 2: Oral consumption of Mirabegron 50 mg slow-release tablets from Astellas Company, England. This study will be repeated on fasting volunteers in a crossover manner at two-week intervals.

Main outcome variables

Maximum plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230222057495N32**
Registration date: **2025-11-11, 1404/08/20**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-11, 1404/08/20**
Update count: **0**

Registration date

2025-11-11, 1404/08/20

Registrant information

Name
Monireh Jalalipour
Name of organization / entity
Nikazma Pars Alborz company
Country
Iran (Islamic Republic of)
Phone
+98 26 3731 8748
Email address
info@naplab.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-01, 1404/08/10

Expected recruitment end date

2026-11-01, 1405/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Bioequivalence study of Mirabegron 50 mg slow-release tablets from Teb Mofid Nikan Pharmaceutical Company compared to Mirabegron 50 mg slow-release tablets from Astellas, UK, on healthy volunteers

Public title
Bioequivalence study of Mirabegron 50 mg extended-release tablets

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy volunteers between the ages of 18 and 55. Body mass index less than 30 kg/m2. All volunteers must be non-smokers.

Exclusion criteria:
Blood pressure less than 90 on 60 mm Hg or more than 140 on 90 mm Hg. Consumption of any drug, alcohol or tobacco within 2 weeks before receiving the drug

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: **36**

Randomization (investigator's opinion)
Not randomized

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
Research Institute of Pharmaceutical Sciences, Tehran University of Medical Sciences

Street address
Institute of Pharmaceutical Sciences, Faculty of Pharmacy, Tehran University of Medical Sciences, Porsina Street

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2025-10-19, 1404/07/27

Ethics committee reference number
IR.TUMS.TIPS.REC.1404.104

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Maximum plasma concentration of mirabegron

Timepoint
Before starting the drug and: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8,10, 24, 48 and 72 hours after taking the drug

Method of measurement
Liquid chromatography - mass spectrometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Includes oral administration of Mirabegron 50 mg slow-release tablets from Teb Mofid Nikan Pharmaceutical Company, Iran, on 24 healthy fasting volunteers. 5 ml of blood is collected from the volunteers at intervals before drug administration and: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10, 24, 48 and 72 hours after drug administration. The study is a cross-over study consisting of two phases (oral administration of one Mirabegron 50 mg slow-release tablet per study and a total of 2 times) with a two-week period (when the drug is completely eliminated from your blood). Determination of plasma levels of Mirabegron is performed by liquid chromatography-mass spectrometry.

Category
Other

2

Description
Intervention group 2: Includes oral administration of Mirabegron 50 mg slow-release tablets from Astellas, UK, to 24 healthy volunteers on an empty stomach. 5 ml of blood is collected from the volunteers at intervals before starting the drug and: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10, 24, 48 and 72 hours after taking the drug. The crossover study consists of two phases (oral administration of one Mirabegron 50 mg slow-release tablet per study and a total of 2 times) with a two-week washout period (when the drug is completely removed from your blood). Determination of plasma Mirabegron concentration is performed by liquid chromatography-mass spectrometry.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Nik Azma Pars Alborz Laboratory
Full name of responsible person
Monireh Jalalipour
Street address
No. 3, Dead End 3 East, Sarvestan Street, Next to Atmosfer
City
Garmdareh Karaj
Province
Alborz
Postal code
3163833487
Phone
+98 26 3731 5789
Email
info@naplab.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Teb Mofid Nikan Pharmaceutical Company
Full name of responsible person
Badri Shahmir
Street address
23rd Street, Phase 3
City
Hashtgerd Industrial Town
Province
Alborz
Postal code
1514638616
Phone
+98 21 9200 1670
Email
info@mifidpharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Teb Mofid Nikan 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
Nik Azma Pars Alborz Laboratory
Full name of responsible person
Monireh Jalalipour
Position
Responsible Pharmacist
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
No. 3, Dead End 3 East, Sarvestan Street, Next to Atmosfer
City
Garmdareh Karaj
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Nik Azma Pars Alborz Laboratory
Full name of responsible person
Monireh Jalalipour
Position
Responsible Pharmacist
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Nik Azma Pars Alborz Laboratory

Full name of responsible person
Monireh Jalalipour

Position
Responsible Pharmacist

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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available