Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the combined effectiveness of mirabegron and biofeedback therapy in the treatment of overactive bladder in women between 35 and 70 years old in a randomized clinical trial.

Protocol summary

Study aim
Evaluating the effectiveness of combined mirabegron therapy and biofeedback sessions in the treatment of overactive bladder syndrome in women aged 35–70 years.

Design
This is a single-center, randomized, parallel-group clinical trial using block randomization.

Settings and conduct
Participants will be recruited from Nikan Aghdasieh Clinic and randomly allocated to one of the two study groups after eligibility assessment and informed consent.

Participants/Inclusion and exclusion criteria
Eligible participants are women with at least a 3-month history of urinary urgency, urinary frequency of more than times per 24 hours, and at least one urgency urinary incontinence episode per day. Exclusion criteria include unwillingness to participate or lack of informed consent, psychiatric or cognitive disorders affecting cooperation, and physical disabilities preventing study interventions.

Intervention groups
Participants in the intervention group will receive mirabegron 50 mg daily plus biofeedback therapy (two sessions per week, 30–45 minutes each). The control group will receive mirabegron 50 mg daily alone.

Main outcome variables
severity of overactive bladder symptoms; quality of life associated with overactive bladder syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230629058615N11**
Registration date: **2026-01-11, 1404/10/21**
Registration timing: **prospective**

Last update: **2026-01-11, 1404/10/21**
Update count: **0**

Registration date
2026-01-11, 1404/10/21

Registrant information

Name
Amir Rezazadeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-03-05, 1404/12/14

Expected recruitment end date
2026-05-14, 1405/02/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the combined effectiveness of mirabegron and biofeedback therapy in the treatment of overactive bladder in women between 35 and 70 years old in a randomized clinical trial.

Public title

Evaluation of the combined effectiveness of mirabegron and biofeedback therapy in the treatment of overactive bladder in women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female participants Age range from 35 to 70 years old Participants who are diagnosed with Overactive Bladder Syndrome Visitors to Nikan Aghdasieh Clinic Urinary urgency for at least 3 months prior to study entry Urinary frequency of 8 or more times in 24 hours At least 1 episode of urge incontinence in 24 hours

Exclusion criteria:

Unwillingness to participate in the study or failure to provide informed consent The presence of mental or cognitive disorders such as schizophrenia, panic disorder, severe obsessive-compulsive disorder, alcohol abuse, and drug abuse that could interfere with the ability to cooperate with the study protocol or affect study outcomes. Physical problems or disabilities that prevent the implementation of study interventions Having specific medical conditions or comorbidities, including urinary tract infection, pelvic or bladder malignancy, pelvic prolapse, bladder and pelvic surgery in the last 6 months, multiple sclerosis, Parkinson's disease, spinal cord injury, diabetic neuropathy, pregnancy or breastfeeding, pelvic radiotherapy and endometriosis that affects the study results.

Age

From **35 years** old to **70 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants will be randomly assigned to one of two treatment groups: Mirabegron with biofeedback or Mirabegron alone, after screening for inclusion and exclusion criteria and providing written informed consent. Randomization will be conducted using Sealed Envelope (www.sealedenvelope.com) with a block randomization method to ensure balanced allocation across groups. Block sizes may be fixed or variable, minimizing the risk of predicting the sequence of assignments. Randomization is performed in 11 variable blocks of 2, 4, and 6.. Each participant will receive a unique identifier generated by the system to maintain confidentiality and facilitate accurate tracking of study data.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Research and Technology Deputy, 5th floor, Central Headquarters, Iran University of medical sciences, Shahid Hemmat Gharb Highway between Sheikh Fadlallah and Shahid Chamran intersections, Tehran

City

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Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2025-10-31, 1404/08/09

Ethics committee reference number

IR.IUMS.REC.1404.803

Health conditions studied

1

Description of health condition studied

overactive bladder (OAB)

ICD-10 code

N32.81

ICD-10 code description

Overactive bladder

Primary outcomes

1

Description

Urinary urgency severity

Timepoint

Assessment in three time intervals: at the beginning of the study in week zero after the start of the intervention, week four after the start of the intervention, week eight after the start of the intervention.

Method of measurement

OAB-V8 questionnaire and OAB-q questionnaire

2

Description

Frequency of urinary incontinence episodes

Timepoint

Assessment in three time intervals: at the beginning of

the study in week zero after the start of the intervention, week four after the start of the intervention, week eight after the start of the intervention.

Method of measurement

OAB-V8 questionnaire and OAB-q questionnaire

3

Description

Improvement of urinary symptoms

Timepoint

Assessment in three time intervals: at the beginning of the study in week zero after the start of the intervention, week four after the start of the intervention, week eight after the start of the intervention.

Method of measurement

OAB-V8 questionnaire and OAB-q questionnaire

Secondary outcomes

1

Description

Comparison of the number of urinations in 24 hours cumulatively

Timepoint

Assessment within 2 weeks after the start of the intervention between the two study groups

Method of measurement

observation and checklist

2

Description

Comparison of the cumulative number of urinations in 24 hours between two study groups

Timepoint

Assessment within 2 weeks after the start of the intervention between the two study groups

Method of measurement

observation and checklist

3

Description

Evaluation of the cumulative reduction in the number of urinary urgency episodes

Timepoint

Assessment within 2 weeks after the start of the intervention between the two study groups

Method of measurement

observation and checklist

4

Description

Evaluation of the cumulative reduction in the number of bedwetting episodes

Timepoint

Assessment within 2 weeks after the start of the intervention between the two study groups

Method of measurement

observation and checklist

5

Description

Evaluation of the safety and tolerability of the treatment related complications

Timepoint

Assessment within 2 weeks after the start of the intervention between the two study groups

Method of measurement

observation and checklist

Intervention groups

1

Description

Intervention group: Participants in this group will receive 50 mg extended-release mirabegron tablets manufactured by Teb Mofid Nikan Pharmaceutical Company (Mirabegral) daily along with biofeedback sessions. Biofeedback sessions will be held 2 sessions per week and each session will last 30 to 45 minutes.

Category

Treatment - Drugs

2

Description

Control group: The control group will include those receiving 50 mg extended-release mirabegron tablets manufactured by Teb Mofid Nikan Pharmaceutical Company (Mirabegral) daily alone and without biofeedback sessions.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikan Aghdasieh Clinic

Full name of responsible person

Bahareh Farajvajari

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No.6, 22 Bahman street, Artesh Blvd., Aghdasieh, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
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Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The final results of scoring the inflammation status, pain, and related parameters
When the data will become available and for how long
After publishing the related article in international journals
To whom data/document is available
Researchers in the field of medicine and pharmacy
Under which criteria data/document could be used
Development of science and expand evidence related to treatment in further research
From where data/document is obtainable
Related journal
What processes are involved for a request to access data/document
Using the journal email to communicate and register a request to use the study data
Comments