Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

A Randomized Clinical Trial Comparing the Efficacy of Mirabegron and Anticholinergic Medications in the Treatment of Urinary Dysfunction in Patients with Overactive Bladder

Protocol summary

Study aim

Comparison of the effects of two treatment approaches (mirabegron , anticholinergic drugs) on changes in urinary dysfunction in patients with overactive bladder.

Design

A phase 2, parallel-group, single-blind, randomized clinical trial on 284 patients. All statistical analyses will be performed using Stata software (StataCorp LLC, College Station, TX, Version 17.

Settings and conduct

The aim of this randomized, single-blind study is to compare the effects of two therapeutic approaches (mirabegron and anticholinergic drugs) on changes in urinary dysfunction in patients with overactive bladder referring to the Pelvic Clinic of Imam Khomeini Hospital located in Tehran. Half of the patients will be assigned to the mirabegron group and half to the anticholinergic group. The sequence of patient allocation in each block will be randomly selected from among the possible combinations. Allocation will be done using opaque, sealed, waxed, and numbered envelopes to maintain allocation concealment.

Participants/Inclusion and exclusion criteria

The main inclusion criteria: Urination more than eight times in a 24 hour period, Urinary urgency with or without urge incontinence, aged 20-70 years, Providing written informed consent. The main exclusion criteria; Active urinary tract infection, pregnancy, breastfeeding or less than 6 months after giving birth, history of surgery to treat incontinence or pelvic prolapse, fecal incontinence or spinal cord injuries, serious illnesses: cancer, kidney, heart, lung disease, diabetes, epilepsy or history of seizures, uncontrolled blood pressure, rheumatism, physical disabilities, dementia or severe psychiatric disorders, drug, alcohol or tobacco use

Intervention groups

Intervention 1 Group 1; Anticholinergic drug solifenacin 5 mg or Vesicare daily; for 8 weeks Intervention 2 Group 2; Mirabegron 50 mg oral tablet daily for 8 weeks

Main outcome variables

Improve urinary dysfunction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230514058174N1**
Registration date: **2026-01-29, 1404/11/09**
Registration timing: **prospective**

Last update: **2026-01-29, 1404/11/09**
Update count: **0**

Registration date

2026-01-29, 1404/11/09

Registrant information

Name

Narges Aghaesmaeili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3627 7163

Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-02-04, 1404/11/15

Expected recruitment end date

2027-02-04, 1405/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Randomized Clinical Trial Comparing the Efficacy of Mirabegron and Anticholinergic Medications in the Treatment of Urinary Dysfunction in Patients with Overactive Bladder

Public title

Comparing the Efficacy of Mirabegron and Anticholinergic Medications in the Treatment of Urinary Dysfunction in Patients with Overactive Bladder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of OAB by a gynecologist based on the following criteria: Urination more than eight times in a 24 hour period, Urinary urgency with or without urge incontinence, aged 20-70 years, Providing written informed consent.

Exclusion criteria:

Active urinary tract infection, pregnancy, breastfeeding or less than 6 months after giving birth, history of surgery to treat incontinence or pelvic prolapse, fecal incontinence or spinal cord lesions, serious illnesses: cancer, Kidney, heart, lung disease, diabetes, epilepsy or history of seizures, uncontrolled blood pressure, rheumatism, physical disabilities, dementia or severe psychiatric disorders, drug, alcohol or tobacco use Unwillingness or inability to follow treatment, occurrence of serious drug side effects (especially to anticholinergics), presence of anatomical abnormalities resulting from surgery in the urinary system (ductal stricture, prolapse, obstructive tumor, fibrosis after radiation therapy, trauma, or iatrogenic surgery), Dysfunction of the lower nervous system of the bladder.

Age

From **20 years** old to **70 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **248**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Sampling was first carried out purposively and then using block randomization or randomization software, in this study, randomization of patients to two intervention groups (mirabegron, anticholinergic drugs) will be done in a 1:1 ratio and using a variable-size block randomization method. In this study, 284 patients with overactive bladder will be randomly assigned to two different treatment groups. The treatment groups will include the mirabegron treatment group and the anticholinergic drug treatment group. 142 people will be equally assigned to each of these groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Imam Khomeini Hospital Complex - Tehran University of Medical Sciences (Research Ethics Committee)

Street address

Imam Khomeini Hospital Complex, Vali Asr Hospital, Bagherkhan Ave.

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2025-12-02, 1404/09/11

Ethics committee reference number

IR.TUMS.IKHC.REC.1404.397

Health conditions studied

1

Description of health condition studied

Overactive bladder, Urinary incontinence

ICD-10 code

N39.8

ICD-10 code description

Other specified disorders of urinary system

Primary outcomes

1

Description

Body Mass Index(BMI)

Timepoint

Prior to intervention

Method of measurement

Standard urinary incontinence questionnaire and testing Urodynamic

2

Description
Urinary frequency
Timepoint
Prior to intervention
Method of measurement
Standard Urinary Incontinence Questionnaire and Flowmetry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: The treatment group includes the mirabegron treatment group, 142 people will be allocated to this group. Randomization of participants will be done using block randomization with a size of 20 people (14 blocks of 20 people and a final block of 4 people), so that in each block, half of the patients will be placed in the first intervention group of mirabegron and half in the second intervention group of anticholinergic. The sequence of patient allocation in each block will be randomly selected from possible combinations, and allocation will be done using opaque, sealed, and numbered envelopes to maintain allocation concealment. Due to the clear difference in intervention type, blinding of participants is not possible; However, the assessor of the patients' symptoms will be unaware of their treatment group (single blind). The first group will be treated with Mirabegron (Tasnim Gostar Company, made in Iran) 50 mg daily for 8 weeks.
Category
Treatment - Drugs

2

Description
Intervention group 2: The treatment group with anticholinergic drugs will be assigned to 142 people. Randomization of participants will be done using block randomization with a size of 20 people (14 blocks of 20 people and a final block of 4 people), so that in each block, half of the patients will be placed in the first intervention group of mirabegron and half in the second intervention group of anticholinergic. The sequence of patient allocation in each block will be randomly selected from possible combinations, and allocation will be done using opaque, sealed, and numbered envelopes to maintain allocation concealment. Due to the clear difference in intervention type, blinding of participants is not possible; However, the assessor of the patients' symptoms will be unaware of their treatment group (single blind). The second group will take anticholinergic drugs such as Solifenacin 5mg or Vesicare (Behestan Daru Company, made in Iran) daily for 8 weeks. This intervention will be performed only once at the beginning of the study. Patients will be assessed twice (before the intervention and 8 weeks after).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex, Vali Asr Hospital
Full name of responsible person
Narges Aghaesmaeili
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
Central Organization of Tehran University of Mesical Sciences, corner of Qods Street, Keshavarz Boulevard
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Narges Aghaesmaeili
Position
Assistant Fellowship
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Specialist
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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
The related data is not 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
Yes - There is 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
Title and more details about the data/document
Some part of above research is possible to be shared.
When the data will become available and for how long
The possibility for sharing of related data will be after 6 months of publishing article.
To whom data/document is available
Only for employed researchers in university and scientific institutes
Under which criteria data/document could be used
The carry out of analysis based on specified values in this research
From where data/document is obtainable
Narges Aghaesmaeili Email: dr.narges.aghaesmaeili@gmail.com Address: No.13 , Sina Alley, Hafez Alley, Bijan Alley, Hakim Nezami Street
What processes are involved for a request to access

data/document

The based on approval of Professor

Comments