Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Tamsulosin effect on the treatment of urinary tract obstruction symptoms in women

Protocol summary

Study aim
Determining the effect of Tamsulosin on treatment of urinary obstruction symptoms in women

Design
Clinical trial with only intervention group, without blinding, phase 2 on 110 patients, data are entered into spss20 software after collection. Quantitative variables will be presented as mean and standard deviation, and qualitative variables will be presented as frequency.

Settings and conduct
Patients with obstructive symptoms Referred to Vaesi Hospital in Sabzevar and Private Urology Practice in Sabzevar are included in the study. First, the IPSS symptoms questionnaire is completed for patients. Then patients are subjected to uroflowmetry and determination of residual disease. Then Tamsulosin drug is taken at a dose of 0.4 mg once a day before going to bed for 1 month. The data before and after the intervention are statistically analyzed and compared since all the participants were treated with the same drug and the same dosage (0.4 ml g once a day) and there is no need to blind the samples.

Participants/Inclusion and exclusion criteria
Women up to 18 YO with urinary tract obstruction symptoms that did not find a reason for the obstruction symptoms in the investigations and the obstruction symptoms did not develop acutely.

Intervention groups
Patients with obstructive symptoms are included in the study. First, the IPSS symptoms questionnaire is completed for patients. Then all patients are subjected to uroflowmetry and determination of residual disease. Then Tamsulosin drug is taken for all patients at a dose of 0.4 mg once a day before going to bed for 1 month.

Main outcome variables
IPSS questionnaire score; Uroflowmetry results, urinary residual amount

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230501058042N1**
Registration date: **2023-05-10, 1402/02/20**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-10, 1402/02/20**
Update count: **0**

Registration date
2023-05-10, 1402/02/20

Registrant information

Name
Taranom Rabiee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4467 2748

Email address
rabiet94@medsab.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-04, 1402/02/14

Expected recruitment end date
2023-06-04, 1402/03/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Tamsulosin effect on the treatment of urinary tract obstruction symptoms in women

Public title
Tamsulosin effect on the treatment of urinary tract obstruction symptoms in women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Female Over 18 years old With urinary tract obstruction symptoms
Exclusion criteria:
Age
From **18 years** old to **60 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences
Street address
Sabzevar Medical Sciences Campus, Shuhada Nuclear Martyrs Boulevard, Sabzevar city
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617614615
Approval date
2023-04-30, 1402/02/10
Ethics committee reference number
IR.MEDSAB.REC.1402.013

Health conditions studied

1

Description of health condition studied
Urinary obstruction symptoms
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
IPSS Score
Timepoint
At the beginning of the study and 4 weeks after taking the drug
Method of measurement
IPSS questionnaire

Secondary outcomes

1

Description
The result of uroflowmetry
Timepoint
The beginning of the study and 4 weeks after the start of taking the drug
Method of measurement
Objective uroflowmetry

Intervention groups

1

Description
Intervention group: Tamsulosin drug with a dose of 0.4 mg daily
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Vasi Hospital
Full name of responsible person
Tarnam Rabiei
Street address
Nuclear martyrs boulevard
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Razavi Khorasan
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Email

rabiet94@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Amin Lotfi

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Amin Lotfi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Taranom Rabie

Position

student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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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
Data is shared after de-identifying individuals.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Accessible to all
Under which criteria data/document could be used
There are no special conditions.
From where data/document is obtainable
rabiet94@medsab.ac.ir
What processes are involved for a request to access data/document
Send your request to the above email.
Comments