

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

rabet94@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

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617614615

Phone

+98 51 4465 1306

Email

rabet94@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Amin Lotfi

Street address

Nuclear martyrs boulevard

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617614615

Phone

+98 51 4401 8001

Email

rabet94@medsab.ac.ir

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

Street address

Nuclear martyrs boulevard

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617614615

Phone

+98 51 4401 8001

Email

rabet94@medsab.ac.ir

Person responsible for scientific 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

Street address

Nuclear martyrs boulevard

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617614615

Phone

+98 51 4401 8001

Email

rabet94@medsab.ac.ir

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

Street address

Nuclear martyrs boulevard

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617614615

Phone

+98 51 4467 2748

Email

rabet94@medsab.ac.ir

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