

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

A comparison of the effect of Tamsulosin and placebo in the treatment of urinary tract disorder in women

Protocol summary

Study aim

A comparison of the effect of Tamsulosin and Placebo in the treatment of urinary tract disorder in women

Design

Clinical trial, community based, parallel group, double blind, randomised controlled trial

Settings and conduct

This study was conducted in Tabriz Hospital and participants through simple randomization divided into intervention and control groups, and double blind study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women with at least three months urination problems; age between 18 to 65 years old; signing informed consent form. Exclusion criteria: active urinary tract infection; history of neurological disorders; pregnant women.

Intervention groups

Intervention group percieve tamsulosin and control group percieve placebo

Main outcome variables

Prevention of urinary retention and urinary complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200111046086N1**

Registration date: **2020-03-31, 1399/01/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-31, 1399/01/12**

Update count: **0**

Registration date

2020-03-31, 1399/01/12

Registrant information

Name

Changiz Naseri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

ch.naseri@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effect of Tamsulosin and placebo in the treatment of urinary tract disorder in women

Public title

Tamsulosin for treatment of urinary tract disorder in women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with at least three months of urinary tract disorder Age between 18 to 65 years old Signing informed consent form

Exclusion criteria:

Active urinary tract infection History of neurological disorders Pregnant women

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **252**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blinded study and researcher and patients are kept unaware of intervention in each group and In order to allocation concealment, the type of intervention will be written on paper and placed in numbered, matte and packed envelopes. The envelopes will be opened in the order of participation of the participants and the type of group will be determined.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Tabriz University Of Medical Sciences.

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

33357313

Approval date

2020-01-06, 1398/10/16

Ethics committee reference number

IR.TBZMED.REC.1398.1056

Health conditions studied

1

Description of health condition studied

Retention of urine

ICD-10 code

Retention

ICD-10 code description

R33

Primary outcomes

1

Description

Urinary symptoms (urgency; frequency; nocturia; dysuria; incomplete emptying)

Timepoint

1 Weeks after intervention

Method of measurement

Standard questionnaire (USSQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tamsulosin capsule with a dose of 0.4 mg made in Iran, one daily for a maximum of 4 weeks

Category

Treatment - Drugs

2

Description

Control group: placebo capsule made in Iran, one daily for a maximum of 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza educational and treatment center

Full name of responsible person

Changhis Naseri

Street address

Department of Urology, Imam Reza educational and treatment center, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3334 7054

Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohsen Mohammad Rahimi

Street address

Central building of Tabriz University of Medical Sciences, Golgasht avenue, Azadi street

City

Tabriz

Province

East Azarbaijan

Postal code

5156954567

Phone

+98 41 3335 5921

Email

mm.rahimi1357@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Sakineh Haj Eebrahimi

Position

Professor of Urology, Fellowship in Female Urology

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Department of Urology, Imam Reza educational and treatment center, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3334 7054

Email

hajebrahimis@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Sakineh Hajebrahimi

Position

Professor of Urology, Fellowship in Female Urology

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Department of Urology, Imam Reza educational and treatment center, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3334 7054

Email

hajebrahimis@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Sakineh Haj Eebrahimi

Position

Professor of Urology, Fellowship in Female Urology

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Department of Urology, Imam Reza educational and treatment center, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3334 7054

Email

hajebrahimis@gmail.com

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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to

make this available

Title and more details about the data/document

A portion of the data that represents the final outcome

When the data will become available and for how long

Access will be 6 months after the results are printed.

To whom data/document is available

All Physicians and residents of the department of Urology

Under which criteria data/document could be used

After obtaining permission from the deputy research of group

From where data/document is obtainable

Person responsible for scientific accountability of study

What processes are involved for a request to access data/document

First approved by the Research Vice-President

Comments