

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of Tamsulosin and Placebo on prevention of urinary retention after Herniorrhaphy, Varicocelelectomy, and Anorectal Surgery.

Protocol summary

Study aim

Determination of the effect of Tamsulosin and Placebo on prevention of urinary retention after Herniorrhaphy, Varicocelelectomy, and Anorectal Surgery.

Design

Clinical trials with a control group, with parallel groups, double-blind, randomized.

Settings and conduct

This study will be conducted to evaluate the effect of Tamsulosin and Placebo on prevention of urinary retention after Herniorrhaphy, Varicocelelectomy, and Anorectal Surgery in Vasei Hospital of Sabzevar. Patients will be randomly assigned to the intervention (0.4 mg Tamsulosin capsule) and control (placebo) group. The response to treatment is evaluated using 24-hour urine volume measurements for study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients under the age of 50 years, Patients undergoing urology or general surgery.
Exclusion criteria: Patients with the symptoms of urinary tract infection before surgery, Patients with a history of urinary retention, Patients with a history of neurological disease, Patients with a history of pelvic surgery, Patients with a history of using Benzodiazepine, beta-agonists, and alpha-agonist prior to surgery

Intervention groups

Intervention group: Patients in this group receive 3 doses of Tamsulosin capsule 0.4 mg (2 doses prior to surgery 12 hours apart and one dose 6 hours after surgery) orally. Control group: Patients in this group receive 3 doses of placebo capsules (2 doses prior to surgery, 12 hours apart and one dose 6 hours after surgery) orally.

Main outcome variables

Determine urinary retention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181006041252N12**

Registration date: **2019-06-18, 1398/03/28**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-18, 1398/03/28**

Update count: **0**

Registration date

2019-06-18, 1398/03/28

Registrant information

Name

Mohammad Sahebkar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 4401 8337

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sahebkar@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Tamsulosin and Placebo on prevention of urinary retention after Herniorrhaphy, Varicocelelectomy, and Anorectal Surgery.

Public title

Comparison of the effect of Tamsulosin and Placebo on prevention of urinary retention after Herniorrhaphy, Varicocelelectomy, and Anorectal Surgery.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients under the age of 50 years Patients undergoing urology or general surgery

Exclusion criteria:

Patients with the symptoms of urinary tract infection before surgery Patients with history of urinary retention Patients with a history of neurological disease Patients with a history of pelvic surgery Patients with a history of using Benzodiazepine, beta-agonist and alpha-agonist prior to surgery

Age

To 50 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 150

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was conducted based on a permutation block by a statistical consultant using random allocation software and the output sequences A and B are available to the researcher, Accordingly, 6 blocks were allocated to patients, in each block, 2 from A treatment group, 2 from the B treatment group were placed. Eventually, after completing the blocks group A was treated with Group A is treated with Tamsulosin 0.4 mg and Group B is being treated with placebo. First, we determine all sixsome modes in which two individuals are assigned to group A and two to group B. Then we assign one of the digits 1 to 6 to each of the sixsome combinations (which includes thirty-six modes). In the next step, we must randomly select 6 blocks of six and write their combinations in succession. For this we have to make 6 samplings with replacement from a six-member community; 6 times, choose a random number between 1 and 6 and this process will continue until the end of the sampling and the difference between the two groups will not exceed a maximum of two (half the size of the block).

Blinding (investigator's opinion)

Double blinded

Blinding description

Each person in the study will be assigned code A and B, that the researcher will only be known of the type of

groups. Clinical care and participants are unaware of the groups. It should be noted that Tamsulosin and placebo are similar in appearance, color, and packaging.

Placebo

Used

Assignment

Parallel

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 University of Medical Sciences, Tohid Blvd, Sabzevar city

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Approval date

2016-06-20, 1395/03/31

Ethics committee reference number

IR.MEDSAB.REC.1395.40

Health conditions studied

1

Description of health condition studied

Urinary retention

ICD-10 code

N20.9

ICD-10 code description

Urinary calculus, unspecified

Primary outcomes

1

Description

Determine urinary retention

Timepoint

At the beginning of the study (before the intervention) and 24 hours after the intervention.

Method of measurement

Measuring urine volume in 24 hours (less than 200 cc)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group receive 3 doses of Tamsulosin capsule 0.4 mg (2 doses prior to surgery 12 hours apart and one dose 6 hours after surgery) orally.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group receive 3 doses of placebo capsules (2 doses prior to surgery, 12 hours apart and one dose 6 hours after surgery) orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei hospital

Full name of responsible person

Mohammad Sahebkar

Street address

Vasei Hospital, Asadabady Ave., Sabzevar Town

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshte Ghorat

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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

Dr. Hamidreza Baghani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for updating data

Contact

Name of organization / entity

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Medical student

Latest degree

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Other areas of specialty/work

General Practitioner

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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

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

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

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable