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, Varicocelectomy, and Anorectal Surgery.

Protocol summary

Study aim
Determination of the effect of Tamsulosin and Placebo on prevention of urinary retention after Herniorrhaphy, Varicocelectomy, 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, Varicocelectomy, 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 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)

Phone
+98 51 4401 8337

Email address
sahebkarm@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, Varicocelectomy, and Anorectal Surgery.

Public title
Comparison of the effect of Tamsulosin and Placebo on prevention of urinary retention after Herniorrhaphy, Varicocelectomy, 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
Sabzevar
Province
Razavi Khorasan
Postal code
9613873136
Phone
+98 51 4401 1014
Email
vasei.h@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Dr. Fereshte Ghorat
Street address
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Phone
+98 51 4401 8319
Email
Drghorat@gmail.com
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
Street address
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Phone
+98 51 4401 8378
Email
Hamid.Baghani@yahoo.com

Person responsible for scientific 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

Street address
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town

City
Sabzevar

Province
Razavi Khorasan

Postal code
9617913114

Phone
+98 51 4401 8378

Email
Hamid.baghani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Simin Mehrpouya

Position
Medical student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town

City
Sabzevar

Province
Razavi Khorasan

Postal code
9617913114

Phone
+98 51 4401 8337

Email
Tarannom_life_16@yahoo.com

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