Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Studying the effect of Tamsulosin on postoperative urinary retention in patients undergoing Inguinal hernia repair under spinal anesthesia at IMam sajjad hospital in 2022

Protocol summary

Study aim
Studying prevalence of post operative urinary retention in 2 groups of placebo and tamsulosin and comparing urinary retention of 2 groups

Design
Prospective randomized double-blind placebo-controlled trial

Settings and conduct
All subjects were NPO (nil per os) about 8 hours before the surgery, and during this time, they were given 1 liter of 1/3 2/3 intravenous fluids. They were asked to empty their bladder prior to surgery. All participants went under spinal anesthesia with 2 cc of Marcaine. During the surgery they all received 1 liter of normal saline 0.9% intravenously. The following 4-6 hours after surgery, they were maintained NPO and received another 1 liter of 1/3 2/3. Following surgery, all subjects were closely monitored for 24 hours by the responsible nurse and the surgeon in case of developing POUR. Urinary retention was diagnosed if the subject was unable to urinate in the presence of palpable bladder in 24 hours postoperatively, so foley catheterization was performed to relieve patient's discomfort.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age older than 50 years old; unilateral inguinal hernia; being candidate for spinal anesthesia. Exclusion criteria: orthostatic hypotension; strangulated hernia; need for other surgery at the same time.

Intervention groups
Enrolled participants are randomly assigned into two groups. Group A (50 subjects) received 0.4 mg Tamsulosin 8 hours prior to operation, group B (50 subjects) received placebo a gelatinous capsule containing lactose in similar shape and appearance as Tamsulosin 8 hours prior to operation.

Main outcome variables
Postoperative urinary retention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220131053898N1**
Registration date: **2022-02-15, 1400/11/26**
Registration timing: **prospective**

Last update: **2022-02-15, 1400/11/26**
Update count: **0**

Registration date
2022-02-15, 1400/11/26

Registrant information

Name
Seyedeh-Atefe Seyedin Navadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 912 287 7480

Email address
atefe.seyedin98@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-19, 1400/11/30

Expected recruitment end date
2022-06-10, 1401/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studying the effect of Tamsulosin on postoperative urinary retention in patients undergoing Inguinal hernia repair under spinal anesthesia at IMam sajjad hospital in 2022

Public title
Studying the effect of Tamsulosin on postoperative urinary retention in patients undergoing inguinal hernia repair under spinal anesthesia

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age older than 50 years old Unilateral inguinal hernia Candidate for spinal anesthesia

Exclusion criteria:
Bilateral hernia Strangulated hernia General anesthesia Prostate cancer BPH Orthostatic hypotention Concurrent surgery

Age
From **50 years** old

Gender
Male

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block randomization will be used to generate a random sequence. The size of the blocks is selected randomly (blocks of 6 and 4). Each block contains an equal number of each group. Random sequence generation software will be used to generate random sequences. To hide random allocation, opaque envelopes sealed with random sequences will be used. Each random sequence is recorded on a card, and the cards are placed in the envelopes of the order, respectively. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened and the assigned group of the participant is revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
Enrolled patients and the responsible nurse for providing the medications are unaware of the type of medicine used for their case.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mazandaran University of Medical Sciences

Street address
Vali Asr blvd., Jouybar tree way, Imam square

City
Sari

Province
Mazandaran

Postal code
4815733971

Approval date
2022-03-01, 1400/12/10

Ethics committee reference number
IR.MAZUMS.RIB.REC.1400.031

Health conditions studied

1

Description of health condition studied
Post inguinal hernioplasty urinary retention

ICD-10 code
K40.9

ICD-10 code description
Unilateral inguinal hernia, without obstruction or gangrene

Primary outcomes

1

Description
Post operative urinary retention

Timepoint
In the next 24 hours after surgery

Method of measurement
Ability to urinate

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients inguinal hernia is confirmed by physical examination or sonography. All patients are kept NPO(nil per os) 8 hours before the surgery and they receive 1 liter of dextrose saline solution . They receive

tamsulosin 0.4 mg from Abidi company 8 hours before the surgery and 6,12 hours after the surgery .

Category

Prevention

2

Description

Control group: patients inguinal hernia is confirmed by physical examination or sonography. All patients are kept NPO(nil per os) 8 hours before the surgery and they receive 1 liter of dextrose saline solution . They receive a gelatinous capsule containing glucose 8 hours before the surgery and 6,12 hours after the surgery .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Sajjad Hospital

Full name of responsible person

Seyedeh Atefe Seyedin Navadeh

Street address

Enghelab square. Motahhari blvd.

City

ramsar

Province

Mazandaran

Postal code

4691714143

Phone

+98 11 5522 0810

Email

imamsajjadhospitalramsar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Seyedeh-Atefe Seyedinnavadeh

Street address

Vali Asr blvd., Jouybar three way

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 912 287 7480

Email

atefe.seyedin98@yahoo.com

Web page address

Grant name

Mazandaran university of medical sciences, research and technology division

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Hadizadeh Neisanghalb

Position

assistance professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Vali Asr blvd., Jouybar three way

City

Sari

Province

Mazandaran

Postal code

4691710001

Phone

+98 11 5509 1101

Email

h.of.mohammad@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Hadizadeh Neisanghalb

Position

Assistance professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Vali Asr blvd., Jouybar three way, Imam square

City
Sari
Province
Mazandaran
Postal code
4691710001
Phone
+98 11 5509 1101
Email
h.of.mohammad@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Mohammad Hadizadeh Neisanghalb
Position
Assistance professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
Street address
Vali asr blv, jouybar three way, Imam square
City
Sari
Province
Mazandaran
Postal code
4691710001
Phone
+98 11 5509 1101
Email
h.of.mohammad@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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be 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
Specific part of data except personal name and ID would be shared with other researchers in future
When the data will become available and for how long
We can share our data after publishing an article
To whom data/document is available
Researchers from other universities
Under which criteria data/document could be used
They can use it only if they mention the names of the researchers of this study
From where data/document is obtainable
email
What processes are involved for a request to access data/document
Through academic email address
Comments