Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Evaluation of clinical effects of oral tamsulosin in reducing urinary retention after spine surgery

Protocol summary

Study aim
Evaluation of clinical effects of oral tamsulosin in reducing postoperative urinary retention

Design
This study is a randomized, double-blind clinical trial with a control group. With parallel groups on 80 patients, the random allocation process will becompleted with Random allocation software.

Settings and conduct
First, they are selected by sampling method available to qualified people and having inclusion criteria. In the following, the blocking method will be used for random acquisition. The random allocation process will be completed with Random allocation software. Based on this, 17 blocks 4 are created with this software and samples are assigned to each of the two groups and the study site of Imam Khomeini Hospital in Sari

Participants/Inclusion and exclusion criteria
Age over 18 years, gender, ability to complete informed consent form, acceptance of study schedule and surgery time, and the fact that he / she must remain in hospital for at least 1 night after surgery. Withdrawal conditions: Allergy or contraindication to tamsulosin use, severe hypersensitivity to sulfa drugs, current warfarin use, use of Foley catheter, suprapubic catheter or urostomy, dialysis patients or end-stage renal disease Kidney disease, urine volume less than 200 CC, sitting blood pressure in the upper extremities 100 mm Hg, orthostatic hypotension

Intervention groups
Planned elective patients who are candidates for spinal surgery Intervention group receiving tamsulosin capsule to patients candidate for posterior surgery in the spine to reduce urinary retention and control group receiving placebo to patients candidate for posterior surgery in the spine for comparison with the intervention group

Main outcome variables
Remaining volume of wood

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140915019185N5**
Registration date: **2022-02-06, 1400/11/17**
Registration timing: **retrospective**

Last update: **2022-02-06, 1400/11/17**
Update count: **0**

Registration date
2022-02-06, 1400/11/17

Registrant information

Name
kaveh haddadi

Name of organization / entity
mazandaran university of medical science

Country
Iran (Islamic Republic of)

Phone
+98 11 3336 1058

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-21, 1399/10/01

Expected recruitment end date
2021-12-22, 1400/10/01

Actual recruitment start date
2020-12-21, 1399/10/01

Actual recruitment end date
2021-08-23, 1400/06/01

Trial completion date
2021-08-23, 1400/06/01

Scientific title
Evaluation of clinical effects of oral tamsulosin in reducing urinary retention after spine surgery

Public title
Evaluation of clinical effects of oral tamsulosin in reducing urinary retention after spine surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Male and female Ability to complete the informed consent form to participate in the study Accepting the schedule of participation in the study and the time of surgery and the fact that she must remain in the hospital for at least 1 night after surgery

Exclusion criteria:
Sensitivity or contraindication to the use of tamsulosin Severe hypersensitivity to sulfa drugs Use of the current alpha-blocker (alphazosin, doxazosin, prazosin, terazosin, verapamil, tamsulosin) or oral alpha agonists, or the initiation of any of these drugs during the start of the intervention phase of the study, which will cause the patient to drop out. Take warfarin now Use of a Foley catheter, suprapubic catheter or urostomy Dialysis patients or patients with less than 200 cc of urine per day Predicting the patient's inability to use the drug orally after surgery Lack of conscious consent to participate in the study Patients who use a Foley catheter chronically Patients are expected to be transferred to the ICU after surgery. Patients with a history of severe heart failure or major cardiovascular events in the past 6 months Use beta-blockers, acetylcholinesterase inhibitors, or drugs that interfere with tamsulosin and betanacol.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The blocking method will be used for random detection. The random allocation process will be completed with Random allocation software. Accordingly, 17 blocks 6 are created with this software and samples are assigned to each of the three groups. It should be noted that in this study, the patient's informed consent form is first recorded in writing. Participants are then randomly assigned to each group. Used to hide random allocation. Patients and researchers will not know any of the group assignments

Blinding (investigator's opinion)
Double blinded

Blinding description
The SNOSE method is used to hide (blind) random allocation. This method is one of the common methods in concealing random allocation. In this method, first a random sequence is created using Random Allocation software, then based on the sample size of the study, a number of envelopes with aluminum wrappers (in order not to clarify the contents of the envelopes) are prepared and each random sequence is created (The intervention group (control group) is recorded on a card and the cards are placed in the envelopes of the letter, respectively. In order to maintain a random sequence, naming on the outer surface of the envelopes is done in the same way as it was produced with the software (for example: TF8G is written on the envelope and the card inside the intervention envelope). Finally, the lids of the envelopes are glued and placed in a box, respectively. At the beginning of the registration of participants, according to the order of entry of eligible participants to the study, one of the envelopes of the letter is opened and the assigned group of the participant is revealed.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences, Imam Khomeini Hospital, Sari

Street address
Imam Khomeini Hospital, Razi Street Ethics Committee

City
Sari

Province
Mazandaran

Postal code
33131 - 48166

Approval date
2020-11-25, 1399/09/05

Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1399.084

Health conditions studied

1

Description of health condition studied

Urinary retention

ICD-10 code

N32.0

ICD-10 code description

Bladder-neck obstruction

Primary outcomes

1

Description

Urinary retention rate

Timepoint

7 days before surgery and 0 to 2 days after surgery

Method of measurement

sonography

Secondary outcomes

empty

Intervention groups

1

Description

Tamsulosin capsule 4 mg mg daily dose started 7 days before surgery and will continue from zero to 2 days after surgery. The type of oral capsule will be provided to the patient. Urinary retention is prescribed

Category

Treatment - Drugs

2

Description

Placebo capsules 4 /. Mg, which was produced in the Drug Research Center of Mazandaran University of Medical Sciences in a similar way to tamsulosin capsules, started one day 7 days before surgery and will continue from zero to 2 days after surgery. Urinary retention was prescribed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Kaveh Haddadi

Street address

Amir Mazandarani Blvd. Imam Khomeini Hospital, Neurosurgery Department,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saedi

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Moalem Ave

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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

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

Kaveh Haddadi

Position

Associate professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

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Person responsible for scientific inquiries

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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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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