

# 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 be completed 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

k.haddadi@mazums.ac.ir

##### 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,

##### City

Sari

##### Province

Mazandaran

##### Postal code

48166-33131

##### Phone

+98 11 3336 1630

##### Fax

+98 11 3336 1630

##### Email

k.haddadi@mazums.ac.ir

##### Web page address

<https://www.mazums.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Majid Saedi

##### Street address

Moalem Ave

##### City

Sari

##### Province

Mazandaran

##### Postal code

48157-33971

##### Phone

+98 11 3325 7230

##### Fax

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##### Email

m.saedi@mazums.ac.ir

##### Web page address

<https://www.mazums.ac.ir>

#### 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

**Street address**

Amir Mazandarani Ave

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## Person responsible for scientific 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 updating data

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**Full name of responsible person**

Kaveh Haddadi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

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**Email**

k.haddadi@mazums.ac.ir

**Web page address**

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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