

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The effect of alpha-blocker drugs on reducing the irritating symptoms caused by ureteral stent placement in patients undergoing surgery

#### Protocol summary

##### Study aim

Determining the effect of alpha-adrenergic blocking drugs on reducing the excitatory symptoms caused by ureteral stent placement in patients undergoing surgery

##### Design

Clinical trial, without control group, with parallel, double-blind, randomized groups, on 60 patients, permutation block method was used for randomization.

##### Settings and conduct

This study is performed on the effect of alpha-adrenergic blocking drugs on reducing the irritating symptoms caused by ureteral stent placement in patients undergoing surgery in Rock training centers. In patients with urinary tract stones, a ureteral stent will be implanted after the stone is removed. The surgeon and surgical method are the same for all patients under study. Patients are assigned to two treatment groups through the randomized permutation block method, in which 4 blocks are used. The first group is considered A and the second group is B. Includes various permutations (AABB, BBAA, ABAB, BABA, ABBA, BAAB) A randomization list is prepared. Based on the randomization list, the desired treatment is assigned to patients. The first group will be given one dose of trazosine (2 mg) daily, and the second group of tamsulosin (0.4 mg) daily. These drugs are continued until the ureteral stent is removed, which is usually 4 to 6 weeks.

##### Participants/Inclusion and exclusion criteria

All patients with unilateral urinary stenting surgery admitted in hospital

##### Intervention groups

All patients underwent unilateral ureteral stenting surgery receiving alpha-adrenergic blocking drug.

##### Main outcome variables

Determining the effect of alpha-adrenoceptor blocking drugs on reducing the excitatory symptoms caused by ureteral stent placement in patients undergoing surgery in educational and medical centers

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201006048950N3**

Registration date: **2022-01-17, 1400/10/27**

Registration timing: **prospective**

Last update: **2022-01-17, 1400/10/27**

Update count: **0**

##### Registration date

2022-01-17, 1400/10/27

##### Registrant information

##### Name

Mahboobeh Khosravani

##### Name of organization / entity

Arakuniversity of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3417 3505

##### Email address

mahboobkhosravani@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-21, 1401/02/01

##### Expected recruitment end date

2023-03-21, 1402/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of alpha-blocker drugs on reducing the irritating symptoms caused by ureteral stent placement in patients undergoing surgery

## Public title

The effect of alpha-adrenergic blocking drugs on reducing the excitatory symptoms of ureteral stent placement

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

lack of Underlying disease, especially nephrogenic cardiovascular problems, allergies, other urological diseases, urinary retention, diabetes, malignancy in the urinary tract, chronic pelvic pain syndrome, lower urinary tract symptoms No drug addiction Age less than 81 years Informed consent One-sided G stent placement

### Exclusion criteria:

## Age

To **81 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

- Participant
- Data analyser

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients are assigned to two treatment groups through the randomized permutation block method, in which 4 blocks are used. The first group is considered A and the second group is B. Randomization list is prepared from different permutations including (AABB, BBAA, ABAB, BABA, ABBA, BAAB). Based on the randomization list, the desired treatment is assigned to patients. The first group will be given one dose of trazosine (2 mg) daily, and the second group of tamsulosin (0.4 mg) daily. These drugs are continued until the ureteral stent is removed, which is usually 4 to 6 weeks.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

This study will be performed as a double-blind clinical trial and patients who have urinary tract stones will have a ureteral stent implanted after the removal of the stone. The surgeon and the surgical method are the same for all patients under study.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of Arak University of Medical Sciences

##### Street address

Adli Alley, Meysam St., Abbas Abad St., Arak Town

##### City

Arak

##### Province

Markazi

##### Postal code

3813734197

#### Approval date

2022-01-02, 1400/10/12

#### Ethics committee reference number

IR.ARAMU.REC.1400.227

## Health conditions studied

### 1

#### Description of health condition studied

Ureteral canal stenosis

#### ICD-10 code

T83.122

#### ICD-10 code description

Displacement of urinary stent

## Primary outcomes

### 1

#### Description

Reduction of stent-dependent stimulus symptoms

#### Timepoint

Take drug:one dose daily for 4-6 weeks

#### Method of measurement

Questionnaires 1- Symptoms related to stent placement (USSQ) 2- International Prostate Symptoms Questionnaire (IPSS) 3- Quality of Life Questionnaire (QOL)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Patients are receiving trazosin drug

#### Category

Treatment - Drugs

## 2

### Description

Intervention group 2: Patients are receiving tamsulosin drug

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Educational and medical centers of Arak University of Medical Sciences

##### Full name of responsible person

Mahboobeh Khosravani

##### Street address

Adli Alley, Meysam St., Abbas Abad St., Arak TownTown.

##### City

Arak

##### Province

Markazi

##### Postal code

3813734197

##### Phone

+98 86 3224 0507

##### Email

mahboobkhosravani@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Mahboobeh Khosravani

##### Street address

Adli Alley, Meysam St., Abbas Abad St., Arak Town

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##### Phone

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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

Arak 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

Arak University of Medical Sciences

##### Full name of responsible person

Mahboobeh Khosravani

##### Position

Faculty Member

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

mahboobkhosravani@gmail.com

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**Email**

## 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**

Not applicable

**Analytic Code**

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

**Data Dictionary**

Not applicable