Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
his 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
City
Arak
Province
Markazi
Postal code
3813737197
Phone
+98 86 3224 0507
Email
mahboobkhosravani@gmail.com
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
Street address
Adli Alley, Meysam St., Abbas Abad St., Arak Town
City
Arak
Province
Markazi
Postal code
3813734197
Phone
+98 86 3224 0507
Email
mahboobkhosravani@gmail.com

Person responsible for scientific 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
Street address
Adli Alley, Meysam St., Abbas Abad St,. Arak Town
City
Arak
Province
Markazi
Postal code
3813734197
Phone
+98 86 3224 0507
Email
mahboobkhosravani@gmail.com

Person responsible for updating data

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

Street address
Adli Alley., Meysam St., abbas Abad St, Arak Town.

City
Arak

Province
Markazi

Postal code
3813734197

Phone
+98 86 3224 0507

Email
mahboobkhosravani@gmail.com

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