

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jul 2026

### The effects of Amitriptylline and Tamsulocin on the urinary symptoms of patients with ureteral stent, a randomized clinical trial.

#### Protocol summary

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##### Summary

The purpose of this study is to investigate the effects of Amitriptylline and Tamsulocin on the urinary symptoms due to ureteral stent. In this randomized clinical trial study, 210 patients who have urinary obstruction of upper urinary tract who are candidate for unilateral ureteral stent will be randomized into one of the following intervention groups. The patients will receive Tamsulocin, 0.4 mg daily, Amitriptylline, 25 mg/daily, or both Amitriptylline, 25 mg daily and Tamsulocin, 0.4 mg daily for three weeks. The primary outcome of this study is the intensity of urinary symptoms measured by using International Prostate Symptom Score (IPSS), after the completion of the treatment protocol.

##### Recruitment status

**Recruitment complete**

##### Funding source

Bushehr University of Medical Sciences

##### Expected recruitment start date

2013-05-22, 1392/03/01

##### Expected recruitment end date

2014-05-22, 1393/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013041713043N1**

Registration date: **2013-05-14, 1392/02/24**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-05-14, 1392/02/24

##### Registrant information

###### Name

Darab Moshtaghi

###### Name of organization / entity

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Iran (Islamic Republic of)

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###### Email address

##### Scientific title

The effects of Amitriptylline and Tamsulocin on the urinary symptoms of patients with ureteral stent, a randomized clinical trial.

##### Public title

The effects of Amitriptylline and Tamsulocin on the urinary symptoms of patients with ureteral stent

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: The patients who have obstruction of upper urinary tract who are candidate for unilateral ureteral stent  
Exclusion criteria: upper urinary tract infection; urogenital system tumor; history of previous urogenital system surgery; neurogenic bladder; bladder stone; overactive bladder; prostatitis; benign prostatic hyperplasia; pregnancy; age more than 60 years and lower than 20 years old

##### Age

From **20 years** old to **60 years** old

##### Gender

Both

## Phase

3

### Groups that have been masked

No information

### Sample size

Target sample size: 210

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Regional Ethics Committee of Bushehr University of Medical Sciences

##### Street address

Vice-Chancellor for Research, Bushehr University of Medical Sciences Campus, Salman Farsi St,

##### City

Bushehr

##### Postal code

##### Approval date

2013-04-22, 1392/02/02

##### Ethics committee reference number

B-92-15-1

## Health conditions studied

### 1

#### Description of health condition studied

Renal Stone

#### ICD-10 code

N20.1

#### ICD-10 code description

Calculus of Ureter

## Primary outcomes

### 1

#### Description

Urinary Symptoms

#### Timepoint

A week and three weeks after intervention

#### Method of measurement

USSQ questionnaire

## Secondary outcomes

### 1

#### Description

Quality of life

#### Timepoint

A week and three weeks after intervention

#### Method of measurement

IPSS questionnaire

### 2

#### Description

Bacterial Colonisation

#### Timepoint

before intervention and 3 weeks later

#### Method of measurement

culture

## Intervention groups

### 1

#### Description

Group1: tamsulosin 0.4 mg once daily for 3 weeks as well as ciprofloxacin 500 mg twice a day Group 2: amitriptyline 25 mg once daily for 3 weeks and tamsulosin 0.4 mg once daily for 3 weeks as well as ciprofloxacin 500 mg twice a day Group 3: amitriptyline 25 mg once daily for 3 weeks as well as ciprofloxacin 500 mg twice a day

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shohadaye Khalij Fars Hospital

##### Full name of responsible person

##### Street address

##### City

Bushehr

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bushehr University of Medical Sciences

##### Full name of responsible person

Afshin Ostovar

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Vice-Chancellor for Research, Bushehr University of Medical Sciences Campus, Salman Farsi St,

##### City

Bushehr

**Grant name**  
**Grant code / Reference number**  
 1500  
**Is the source of funding the same sponsor organization/entity?**  
 Yes  
**Title of funding source**  
 Bushehr University of Medical Sciences  
**Proportion provided by this source**  
 100  
**Public or private sector**  
 empty  
**Domestic or foreign origin**  
 empty  
**Category of foreign source of funding**  
 empty  
**Country of origin**  
**Type of organization providing the funding**  
 empty

## Person responsible for general inquiries

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
 empty  
**Study Protocol**  
 empty  
**Statistical Analysis Plan**  
 empty  
**Informed Consent Form**  
 empty  
**Clinical Study Report**  
 empty  
**Analytic Code**  
 empty  
**Data Dictionary**  
 empty