Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Summary
The purpose of this study is a to investigate the effects of Amitriptylline and Tamsulocin on the urinary symtoms 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 recieve Tamsulocin, o.4 mg daily, Amitriptylline, 25 mg/daily, or both Amitriptylline, 25 mg daily and Tansulocin, 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.

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
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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

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

Public title
The effects of Amitriptylline and Tamsulocin on the urinary symtoms 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 unirary 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 Reseaech, 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
Street address
Vice-Chancellor for Research, Bushehr University of Medical Sciences Campus, Salman Farsi St,
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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