Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of tamsulosin on relief of ureteral stent discomfort in patients with urolithiasis

Protocol summary

Summary

Objective: Evaluation of the effect of tamsulosin on relief of discomfort caused by ureteral stenting in patients with urolithiasis being treated with transurethral litotripsy. Study design: clinical trial, randomized, double-blind, placebo given control group, multi-center. Study population: patients with unilateral urolithiasis visiting Sinal and Baharlou Hospitals (Tehran, Iran) indicated for treating with transurethral lithotripsy and Double-J stenting thereafter. Major inclusion criteria: age equal to 18 and more, urolithiasis indicated for transurethral litotripsy and Double J ureteral stenting thereafter. Major exclusion criteria: significant ureteral trauma, presence of previous ureteral stent, other concurrent operations, previous prostate resection, bladder tumors, urinary infections, history of chronic pain, pregnancy, age less than 18, prostate cancer, cardiovascular disease, coronary artery disease. Sample size: 70. Intervention being studied: Cap Tamsulosin 0.4 mg. Intervention time: after transurethral litotripsy and ureteral stenting thereafter. Primary outcome: relief of discomfort caused by ureteral stenting.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042221886N2**
Registration date: **2015-05-03, 1394/02/13**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-05-03, 1394/02/13

Registrant information

Name

Parvin Kasiri

Name of organization / entity

Tehran University of Medical Sciences, international branch

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

All the drugs and placebos are provided by Exir Pharmaceutical Company

Expected recruitment start date

2015-05-05, 1394/02/15

Expected recruitment end date

2015-09-06, 1394/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of tamsulosin on relief of ureteral stent discomfort in patients with urolithiasis

Public title

Effect of tamsulosin on reducing discomfort caused by ureteral stenting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age equal to 18 and more; urolithiasis indicated for transurethral litotripsy and Double J ureteral stenting thereafter. Exclusion criteria: significant ureteral trauma; presence of previous ureteral stent; other

concurrent operations; previous prostate resection; bladder tumors; urinary infections; history of chronic pain; pregnancy; age less than 18; prostate cancer; cardiovascular disease, coronary artery disease.

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Poursina St., Tehran, Iran

City
Tehran

Postal code

Approval date
2015-02-24, 1393/12/05

Ethics committee reference number
139116

Health conditions studied

1

Description of health condition studied
Discomfort after ureteral stenting in patients with urolithiasis

ICD-10 code
N20

ICD-10 code description
Calculus of kidney and ureter

Primary outcomes

1

Description
Pain interference with sleep

Timepoint
day 14 of intervention

Method of measurement
questionnaire

2

Description
Pain interference with daily activity

Timepoint
day 14 of intervention

Method of measurement
questionnaire

3

Description
frequency of urination

Timepoint
day 14 of intervention

Method of measurement
questionnaire

4

Description
flank pain

Timepoint
day 14 of intervention

Method of measurement
questionnaire

5

Description
severity of pain during urination

Timepoint
day 14 of intervention

Method of measurement
questionnaire

6

Description
painkiller consumption

Timepoint
day 14 of intervention

Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control with placebo, a capsule similar to the tamsulosin capsule given to case group, contains inactive substance, administered once a day PO, for 14 days.
Category
Placebo

2

Description
Tamsulosin, 0.4 mg capsule, oral administration, once a day for 14 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Street address
City
Tehran

2

Recruitment center
Name of recruitment center
Baharlou Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Exir Pharmaceutical Company
Full name of responsible person
Dr. Shahla Mirazizi
Street address
15, Rahmati Alley, Vlieasr St
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Exir Pharmaceutical Company
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

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Farshad Gholipour
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Person responsible for scientific inquiries

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Urologist, Fellowship of kidney transplantation, assistant professor
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Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Farshad Gholipour

Position
Medical Student
Other areas of specialty/work
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Fax
Email
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Web page address

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