

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 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 lithotripsy. 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 lithotripsy 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 lithotripsy 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)

Phone

+98 21 8889 6694

Email address

p-kasiri@student.tums.ac.ir

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 lithotripsy 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

Position

Medical Student

Other areas of specialty/work

Street address

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

City

Tehran

Postal code

Phone

+98 21 6636 2089

Fax

Email

f-gholipour@student.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahram Gooran

Position

Urologist, Fellowship of kidney transplantation,
assistant professor

Other areas of specialty/work

Street address

Imam Khomeini St., Hasan Abad Sq., Sina Hospital

City

Tehran

Postal code

Phone

+98 21 6634 8500

Fax

Email

shahram_gooran@yahoo.com

Web page address

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**Street address**

Tehran University of Medical Sciences, Poursina St.

City

Tehran

Postal code**Phone**

+98 21 6636 2089

Fax**Email**

f-gholipour@student.tums.ac.ir

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