Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

The study of the effect of tadalafil in comparison with tamsulosin and placebo on the symptoms of double-J stent insertion in ureteral following by transureteral ureteroscopy and lithotripsy in men with ureteral stones

Protocol summary

Summary

The insertion of the ureter stent is accompanied by the morbidity or potential complications of placement and its impact on the patient's quality of life. In this pilot double blind randomized controlled clinical trial, 120 men above 18y with urethral stent who undergone transureteral lithotripsy (TUL) and have DJ-stent will be enrolled. Baseline evaluation consists of filling Ureteric Stent Symptom Questionnaire (USSQ), International Prostate Symptom Score (IPSS) questionnaire. After measuring the pain by VAS scale measurement, patients will randomly divide into 3 groups. The first group will receive 5mg tadalafil, second group will receive 0.4mg tamsulosin and third group will receive placebo. All medications will be prescribed once daily. After 2 and 4 weeks, patients will reevaluate by same questionnaires. All sever pain episodes and analgesic consumption will be record. Antibiotic prophylaxis containing peri-operative injections of cefazolin plus amikacin with appropriate dosage, and post-operative oral ciprofloxacin 500mg twice per day for 3 days, followed by 250mg night dose until the end of the stent insertion period. During postoperative admission in hospital, single dose paracetamol will be injected when necessary. After discharge, acetaminophen 500mg (max 4 times a day for 7 days) and in case of severe pain with no response to acetaminophen, suppository diclofenac 50mg will be administered.Blinding for both groups (for both study subjects and study information analysis and monitoring committee) will be carried out.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702261853N13**

Registration date: **2017-08-14, 1396/05/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-14, 1396/05/23

Registrant information

Name

Siavash Falahatkar

Name of organization / entity

Urology Research Center

Country

Iran (Islamic Republic of)

Phone

+98 13 3352 5259

Email address

urc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Urology Research Center, Guilan University of Medical Sciences

Expected recruitment start date

2015-09-11, 1394/06/20

Expected recruitment end date

2017-06-10, 1396/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the effect of tadalafil in comparison with tamsulosin and placebo on the symptoms of double-J

stent insertion in ureteral following by transureteral ureteroscopy and lithotripsy in men with ureteral stones

Public title
The effect of tadalafil compared to tamsulosin and placebo on the symptoms of double-J stent insertion in men with ureter stones
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: male with age ≥ 18 years; negative U/C; unilateral DJ-stent insertion; testimonial endorsement Exclusion criteria: any underlying disease specially cardiovascular nephrogenic; allergic; other urologic disease; acute urinary retention (AUR); diabetes mellitus (DM); urinary tract malignancy; chronic pelvic pain syndrome (CPPS); Lower Urinary Tract Symptoms (LUTS); bilateral stent; PSA>10 ng/ml or PSA=4-10 ng/ml with positive prostate biopsy for malignancy; recent Extracorporeal shock wave lithotripsy (ESWL); stent malposition; neurogenic bladder; kidney transplant; radiation or chemotherapy; long term treatment with α-blockers, anticholinergic, analgesic, Selective serotonin reuptake inhibitors (SSRIs), diuretics, calcium channel blockers (CCB), lithium; opium addiction; all conditions that urologist prefers to exclude patient.
Age
From **18 years** old to **139 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Random allocation in groups will be done by block randomization (Random Blocks).

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Opposite Sepah Bank, Western Shahid Beheshti Blvd., Gaz Square
City
Rasht
Postal code
41938-93345
Approval date
2015-08-24, 1394/06/02
Ethics committee reference number
IR.GUMS.REC.1394.213

Health conditions studied

1

Description of health condition studied
Lower urinary tract symptoms
ICD-10 code
N21
ICD-10 code description
Calculus of lower urinary tract

2

Description of health condition studied
Pain in the flank and suprapubic areas
ICD-10 code
R10.4
ICD-10 code description
Other and unspecified abdominal pain

3

Description of health condition studied
Sexual function
ICD-10 code
F52.9
ICD-10 code description
Unspecified sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description
Pain in the flank, suprapubic and in voiding time
Timepoint
Before intervention, 2 and 4 weeks after intervention
Method of measurement
By the standard questionnaire of pain measurement (VAS score)

2

Description
Sexual function
Timepoint
Before intervention, 2 and 4 weeks after intervention
Method of measurement
By USSQ standard questionnaire

3

Description
Symptoms related to lower urinary tract after stent inserting (including all obstructive and irritative symptoms)
Timepoint
Before intervention, 2 and 4 weeks after intervention
Method of measurement
By USSQ standard questionnaire and IPSS standard questionnaire

4

Description
Dysuria
Timepoint
Before intervention, 2 and 4 weeks after intervention
Method of measurement
By USSQ standard questionnaire

5

Description
Hematuria
Timepoint
Before intervention, 2 and 4 weeks after intervention
Method of measurement
By USSQ standard questionnaire

Secondary outcomes

1

Description
Need for additional antibiotic intake
Timepoint
2 and 4 weeks after intervention
Method of measurement
By USSQ Standard Questionnaire

2

Description
Impact on the quality of life and work
Timepoint
2 and 4 weeks after intervention
Method of measurement
By USSQ Standard Questionnaire

Intervention groups

1

Description
Intervention group: Tadalafil 5 mg tablet, made in Iran, one daily dose, for 4 weeks
Category
Treatment - Drugs

2

Description
Intervention group: Tamsulosin 0.4 mg tablet, made in Iran, one daily dose, for 4 weeks
Category
Treatment - Drugs

3

Description
Control group: Placebo tablet, made in Iran, one daily dose, for 4 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Dr. Mehdi Sebti (Resident of Urology)
Street address
Sardar Jangal Street, Razi Hospital
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urology Research Centre, Guilan University of Medical Sciences
Full name of responsible person
Head of Urology Research Centre, Dr. Siavsh Falahatkar
Street address
Sardar Jangal Street, Razi hospital, Urology Research Centre
City
Rasht
Grant name
10506
Grant code / Reference number
32
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urology Research Centre, Guilan 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

Contact
Name of organization / entity
Urology Research Center, Guilan University of Medical Sciences
Full name of responsible person
Dr. Keivan Gholamjani Moghaddam
Position
General practitioner / Project ىxecutive
Other areas of specialty/work
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Person responsible for updating data

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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