Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

The comparison of the Efficacy and Safety of Combination of Tamsulosin with Tolterodin and Tamsulosin alone In the Treatment of Double-J Stent Related Urinary Tract Symptoms

Protocol summary

Study aim

Comparison of efficacy and safety of tamsulosin with tolterodine and tamsulosin alone in the treatment of urinary symptoms associated with Double-J stent following urethroscopy and ureteral lithotripsy in patients with kidney stones

Design

The study looked at 50 patients with ureteral stones who would gradually undergo urethroscopy and transurethral lithotripsy according to the sequence of referrals. After obtaining informed written consent to participate in the project, patients will be randomly divided into two groups: Tamsulosin, Tamsulosin with tolterodine.

Settings and conduct

One of the two blind groups will be treated with tamsulosin 0.4 mg, tamsulosin 0.4 mg with toltudine 2mg. Toltrudin 2mg will also be given to patients in similar capsules. The capsules are packaged in packages coded by The physician will be given to the patients and the medication code of each patient will be given to the physician, but the questionnaire will be completed by the third person (student) who does not know the codes.

Participants/Inclusion and exclusion criteria

Entry 1. Patients over 18 years of age 2. Complete the written consent form 3. One-way ureteral stenting after ureteroscopy and TUL for ureteral stones 4. Negative urine culture prior to TUL and stents 5. male Non entry 1. Physician diagnosed sensitivity to tamsulosin, tolterodine or folic acid 2. Establishment of ureteral stent during the last 6 months

Intervention groups

1- Treated with Tamsulosin 0.4 mg capsules per day 2- Treated with Tamsulosin 0.4 mg capsule and tolterodine 2 mg per day

Main outcome variables

All patients with pain in the Flank and Suprapubic areas during stent placement, Frequency, Dysuria, Nakcuri, Hamachuri, Urgency, Incomplete Emptying, Urge Incontinency, work performance and physical activity, sexual function, general health,will be evaluated according to the Urinary Tract Stent Symptoms Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190119042410N1**
Registration date: **2020-07-05, 1399/04/15**
Registration timing: **retrospective**

Last update: **2020-07-05, 1399/04/15**
Update count: **0**

Registration date

2020-07-05, 1399/04/15

Registrant information

Name

Mohammad reza shafaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3552 2722

Email address

po0yan.shafaei08@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date
2019-10-06, 1398/07/14
Actual recruitment end date
2020-06-14, 1399/03/25
Trial completion date
2020-06-14, 1399/03/25

Scientific title
The comparison of the Efficacy and Safety of Combination of Tamsulosin with Tolterodin and Tamsulosin alone In the Treatment of Double-J Stent Related Urinary Tract Symptoms

Public title
The efficacy of combination therapy of toltrodine and tamsulosin on urinary symptoms
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years of age Completion of written consent form One-way ureteral stenting after ureteroscopy and TUL for ureteral stones Negative urine culture prior to TUL and stents male
Exclusion criteria:
Physician diagnosed sensitivity to tamsulosin, toltrodine or folic acid Establishment of ureteral stent during the last 6 months
Age
From **18 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients with inclusion criteria who do not have exclusion criteria will enter the study. Allocation of patients to each of the two intervention groups is done by simple random assignment method. Unit of randomization will be each individual person. Random number tables available at http://www.rand.org/publications/classics/randomdigits will be used for randomization. This table is ordered in blocks of five. The first number in the fist block of first page will be chosen and moving horizontally the first number of each block will be selected. Odds and even number will be allocated to each group.The secretary of clinic extracted all numbers before the start of recruitment of cases. She write all numbers in a list and patients will recieve each intervention according to the list. No more action will be done for allocation concealment.
Blinding (investigator's opinion)
Double blinded
Blinding description
The capsules are provided to patients by the physician encoded packages and the patient's drug code will be provided to the analyst, but completion of the questionnaire will be done by a third person (student) who is not aware of the codes.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Bushehr University of Medical Sciences
Street address
Clinical Research Development Center, Ground floor, Training Hall, Taleghani Ave., Bushehr, Bushehr, Iran
City
Bushehr
Province
Boushehr
Postal code
7517933755
Approval date
2019-05-20, 1398/02/30
Ethics committee reference number
IR.BPUMS.REC.1398.038

Health conditions studied

1

Description of health condition studied
Urinary symptoms caused by stent
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Score from the USSQ Questionnaire
Timepoint
Start studying and two weeks later
Method of measurement
USSQ Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 Tamsulosin 0.4 mg daily for 2 weeks
Category
Treatment - Drugs

2

Description
Intervention group 2 Tamsulosin 0.4 mg daily for 2 weeks and Toltrodine 2 mg daily for 2 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bushehr Persian Gulf Martyrs Hospital
Full name of responsible person
Farshad Zohrabi
Street address
Ayatollah Taleghani Blvd,Bushehr
City
Bushehr
Province
Boushehr
Postal code
7517933755
Phone
+98 77 3345 5375
Email
mpgh@bpums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Boushehr University of Medical Sciences
Full name of responsible person
gholamreza khamisipoor
Street address
Bushehr University of Medical Sciences and Health Services, in front of the Friday prayer place, Moallem Street
City
bushehr
Province
Boushehr
Postal code
7514633341
Phone
+98 77 3345 0178
Email
Pkarshenasan@Yahoo.Com

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

Person responsible for general inquiries

Contact
Name of organization / entity
Boushehr University of Medical Sciences
Full name of responsible person
Farshad zohrabi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Urology
Street address
Bushehr University of Medical Sciences and Health Services, in front of the Friday prayer place, Moallem Street
City
Bushehr
Province
Boushehr
Postal code
7514633341
Phone
+98 77 3332 0657
Email
zohrabi.fsh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Boushehr University of Medical Sciences
Full name of responsible person
Motamed Niloofar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
Street address

Bushehr University of Medical Sciences and Health Services, in front of the Friday prayer place, Moallem Street

City
bushehr

Province
Boushehr

Postal code
7514633341

Phone
+98 77 3332 0657

Email
motamedn@bpums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Boushehr University of Medical Sciences

Full name of responsible person
Shafaei Mohammadreza

Position
Medical student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
Bushehr University of Medical Sciences and Health Services, in front of the Friday prayer place, Moallem Street

City
bushehr

Province
Boushehr

Postal code
7514633341

Phone
+98 77 3332 0657

Email
po0yan.shafaei08@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
There is no further information

When the data will become available and for how long
There is no further information

To whom data/document is available
There is no further information

Under which criteria data/document could be used
There is no further information

From where data/document is obtainable
There is no further information

What processes are involved for a request to access data/document
There is no further information

Comments