

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 tolterodine 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 Tolterodine and Tamsulosin alone In the Treatment of Double-J Stent Related Urinary Tract Symptoms

Public title

The efficacy of combination therapy of tolterodine 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, tolterodine 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 first 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 wrote all numbers in a list and patients will receive 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 Toltrudine 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

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Boushehr

Postal code

7517933755

Phone

+98 77 3345 5375

Email

mpgh@bpums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bushehr 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

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bushehr

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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

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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

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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

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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