Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of the effect of Tamsulosin, Solifenacin and their combination in the treatment of double J stent-related urinary symptoms in patients with ureteral stones

Protocol summary

Study aim

to evaluate the effect of Tamsulosin, Solifenacin and their combination in the treatment of double J stent-related urinary tract symptoms in patients with ureteral stones

Design

A phase 3, single-blinded, sham-controlled randomized clinical trial (RCT) with the parallel-groups design, on 80 patients. Simple individual randomization was done using random numbers table and sealed envelopes.

Settings and conduct

The study was performed in the Ghaem hospital, Mashhad, Iran. It was a single-blind RCT in which the research participants were blinded to the randomization. Each group of patients received the allocated medication following transurethral lithotripsy and double J stent placement. The Ureteral Stent Symptoms Questionnaire (USSQ) questionnaire was used to evaluate the double J stent-related urinary tract symptoms after 2 weeks of stent placement.

Participants/Inclusion and exclusion criteria

Inclusion criteria include the following: age 20 to 60 years, candidate for unilateral stent implantation following TUL (trans ureteral lithotripsy) and informed consent. Exclusion criteria include: history of surgery on the urinary system, urethroscopy or bilateral double j implantation, history of LUTS symptoms following BPH or other urinary tract diseases such as neurogenic bladder and overactive bladder, concomitant use of anti-adrenergic and anti-urinary drugs Cholinergic, pregnancy, drug allergies and finally the occurrence of major complications following surgery

Intervention groups

patients are randomized into 4 groups receiving the following medications respectively: Tamsulosin 0.4 mg once daily, Solifenacin 5 mg once daily, Tamsulosin + Solifenacin with the same dosage, and placebo

Main outcome variables

double J stent-related lower urinary tract symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200831048564N1**
Registration date: **2020-09-17, 1399/06/27**
Registration timing: **retrospective**

Last update: **2020-09-17, 1399/06/27**
Update count: **0**

Registration date

2020-09-17, 1399/06/27

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2020-07-22, 1399/05/01

Trial completion date

2020-07-22, 1399/05/01

Scientific title

Comparison of the effect of Tamsulosin, Solifenacin and their combination in the treatment of double J stent-related urinary symptoms in patients with ureteral stones

Public title

The effect of Tamsulosin and Solifenacin in the treatment of double J stent-related urinary symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with ureteral stones undergoing unilateral transurethral lithotripsy

Exclusion criteria:

History of surgery on the urinary system Performing urethroscopy or double j implantation bilaterally History of LUTS symptoms following BPH Other diseases of the urinary system such as neurogenic bladder and overactive bladder Concomitant use of anti-adrenergic and anticholinergic drugs pregnancy Drug Allergy Occurrence of major complications following surgery

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

More than 1 sample in each individual

Number of samples in each individual: **20**

4 groups: 20 patients in each group

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

simple individual randomization using sealed envelopes. In order to random allocation concealment by SNOSE method First, a random sequence assignment was created using the random number table method that created numbers from 00 to 99. Then based on the total sample size of the research, which is 80 people, 80 envelopes with aluminum wrappers (in order not to clarify the contents of the envelopes) were prepared and each of the random sequences created was recorded on a card and the cards were placed in envelopes. The order was placed. In order to maintain a random sequence on the outer surface of the envelopes, numbering was performed in the same way that A, B, C, and D drug groups were assigned in this envelopes. Accordingly, numbers between 00 to 24 were assigned to A group, number 25 to 49 B group, number 50 to 74 C group, and number 75 to 99 D group. Finally, the letter envelopes were glued and placed in a box, respectively. At the beginning of the registration of participants, based on the order of entry of the participants who met the inclusion criteria, one of the envelopes was opened and the assigned group of the participant was revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Research participants were blinded to the randomization. To maintain blindness, identical-looking medications and placebo without name were used.

Placebo

Used

Assignment

Parallel

Other design features

A phase 3, single-blinded, sham-controlled randomized clinical trial (RCT) with the parallel-groups design of 80 patients. Simple individual randomization was done using sealed envelopes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

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Mashhad, Park Mellat Square, University Campus, Mashhad University of Medical Sciences

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Razavi Khorasan

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9188911111

Approval date

2018-12-18, 1397/09/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.580

Health conditions studied

1

Description of health condition studied

lower urinary tract symptoms, ureteral stone

ICD-10 code

N20.9

ICD-10 code description

Urinary calculus, unspecified

Primary outcomes

1

Description

ureteral stent urinary symptoms

Timepoint
2 weeks after intervention
Method of measurement
Based on Ureteral Stent Symptoms Questionnaire (USSQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1; cap Tamsulosin 0.4 mg once daily for 2 weeks
Category
Treatment - Drugs

2

Description
Intervention group: 2; Tab Solifenacin 5 mg once daily for 2 weeks
Category
Treatment - Drugs

3

Description
Intervention group:3, cap including Tamsulosin 0.4 mg + Solifenacin 5 mg, once daily for 2 weeks
Category
Treatment - Drugs

4

Description
Control group:Tab Placebo (identical-looking with the medication) once daily for 2 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Urology, Mashhad University of Medical Sciences
Full name of responsible person
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1

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Web page address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data is potentially shareable after unidentified individuals
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Researchers of medical universities
Under which criteria data/document could be used
The results of this study are intended to help the medical community to help treat patients
From where data/document is obtainable
Ghaem Hospital, Department of Urology
akhavara@mums.ac.ir
What processes are involved for a request to access data/document
Please request by email
Comments