

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Comparison of the effect of Terazosin, Tolterodine, 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 Terazocine, Tolterodine 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 of 80 patients. Simple individual randomization was done using 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: patients with ureteral stones undergoing transurethral lithotripsy
exclusion criteria: History of major urinary surgery; Benign prostate hyperplasia under medical therapy; Overactive bladder; Drug sensitivity

Intervention groups

patients are randomized into 4 groups receiving the following medications respectively: Terazosin 2 mg twice a day, Tolterodine 2 mg twice a day, Terazocine+Tolterodine 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: **IRCT20160924029935N2**

Registration date: **2020-05-26, 1399/03/06**

Registration timing: **retrospective**

Last update: **2020-05-26, 1399/03/06**

Update count: **0**

Registration date

2020-05-26, 1399/03/06

Registrant information

Name

Seyedalireza Ghoreifinejadian

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3858 3885

Email address

ghoreifina@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-20, 1397/12/29

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

2019-03-20, 1397/12/29

Actual recruitment end date

2020-03-18, 1398/12/28

Trial completion date

2020-03-18, 1398/12/28

Scientific title

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

Public title

The effect of Terazosin and Tolterodine 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 major urinary surgery Benign prostate hyperplasia under medical therapy Overactive bladder Drug sensitivity

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

Blinding (investigator's opinion)

Single blinded

Blinding description

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

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical

Sciences

Street address

Ghoreishi Building, Daneshgah St

City

Mashhad

Province

Razavi Khorasan

Postal code

91357345

Approval date

2018-12-17, 1397/09/26

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.603

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

Ureteral Stent Symptoms Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1; Tab Terazosin 2 mg BID for 2 weeks

Category

Treatment - Drugs

2

Description

Intervention group: 2; Tab Tolterodine 2 mg BID for 2 weeks

Category

Treatment - Drugs

3

Description

Intervention group: 3, Tab including Terazosin 2

mg+Tolterodine 2mg, BID for 2 weeks

Category

Treatment - Drugs

4

Description

Control group: Tab Placebo (identical-looking with the medication) BID 2 for weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Alireza Akhavan Rezayat

Street address

Ahmadabad St

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3840 0001

Email

b.ghaem@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Daneshgah St

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

vresearch@mums.ac.ir

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

Full name of responsible person

Alireza Akhavan Rezayat

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Urology Department, Ghaem Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3840 0001

Fax

Email

akhavanra@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Alireza Akhavan Rezayat

Position

Assistant Professor

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Other areas of specialty/work

Urology

Street address

Urology Department, Ghaem Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3840 0001

Fax

Email

akhavanra@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyedalireza Ghoreifinejadian

Position

Assistant Professor of Urology

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Urology Department, Imam Reza Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 38050

Fax

Email

aghoreifi@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available