

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The comparison of Tolterodine, Tamsulosin, and placebo effects on symptoms of indwelling ureteral stent

Protocol summary

Summary

Today, ureteral stent is a necessary device to relieve upper urinary tract obstruction caused by a variety of etiologies. Symptoms of indwelling ureteral stent are potentially a health problem and have adverse effects on quality of life. The purpose of this clinical trial is to evaluate Tamsulosin and Tolterodine treatment effect on relieving indwelling ureteral stent symptoms. A group of 156 patients, who are going to undergo unilateral ureteral stenting for relieving upper urinary tract obstruction, will be selected based on inclusion and exclusion criteria. After stenting, they will be randomly assigned into three groups to receive four weeks medication with Tamsulosin 0.4mg at night or Tolterodine 2mg two times a day or placebo once per day. They will be prescribed Tramadol 50mg and Acetaminophen 500mg as analgesics -50 tablets of each one- to consume on demand. Patient's symptoms will be evaluated with the Ureteral Symptom Score Questionnaire (USSQ) one and four weeks after ureteral stenting. Their stent will be removed four weeks after insertion. They will be evaluated again with USSQ, one week after stent removal. Finally, amount of analgesic usage of each patient will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812173509N1**
Registration date: **2010-05-09, 1389/02/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-05-09, 1389/02/19

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Kermanshah University of Medical Sciences and Health Services

Expected recruitment start date

2010-03-07, 1388/12/16

Expected recruitment end date

2010-10-08, 1389/07/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of Tolterodine, Tamsulosin, and placebo effects on symptoms of indwelling ureteral stent

Public title

Effective treatment to relieve indwelling ureteral stent symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Ureteral stenting for treatment of ureteral obstruction due to upper tract urinary stone

(kidney or ureter) Exclusion criteria: history of urinary system surgery, BPH (IPSS>7), long standing lower urinary tract symptoms, Indwelling ureteral stent at presentation, treatment with NSAIDs or Alpha-blockers, advanced cardiac or hepatic disease, Pregnancy

Age

From **16 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **156**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences and Health Services Ethical Committee

Street address

No.2 building, Kermanshah University of medical sciences, Shahid Beheshti Blvd, Kermanshah

City

Kermanshah

Postal code

Approval date

2010-02-27, 1388/12/08

Ethics committee reference number

54122

Health conditions studied

1

Description of health condition studied

Symptoms of indwelling ureteral stent

ICD-10 code

T83.5 , T8

ICD-10 code description

Infection and inflammatory reaction due to prosthetic device, implant and graft in urinary system - Unspecified

complication of genitourinary prosthetic device, implant and graft

Primary outcomes

1

Description

Relieving of indwelling ureteral stent symptoms

Timepoint

1 week and 4 weeks after insertion, 1 week after removal

Method of measurement

Ureteral stent symptom score questionnaire (USSQ)

Secondary outcomes

1

Description

Presence of indwelling ureteral stent symptoms in spite of medication

Timepoint

1 week and 4 weeks after insertion, 1 week after removal

Method of measurement

Ureteral stent symptom score questionnaire (USSQ)

Intervention groups

1

Description

Tamsulosin 0.4mg capsule at bedtime for 4 weeks

Category

Treatment - Drugs

2

Description

Tolterodine 2mg tablet two times a day (morning , evening) for 4 weeks

Category

Treatment - Drugs

3

Description

A capsule of Starch daily for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imamreza hospital

Full name of responsible person

Street address

Imamreza hospital - Zakaria Razi Blvd - Kermanshah

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research, Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Dr. Farid Najafi

Street address

Shahid Beheshti Blvd- Kermanshah

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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

Vice-chancellor for research, Kermanshah University of Medical Sciences and Health Services

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

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Full name of responsible person

Dr. Mahmoudreza Moradi

Position

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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