

# 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

Sina Ebrahimi

##### Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1336 6523

##### Email address

sebrahimi@kums.ac.ir

#### 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

**City**

Kermanshah

**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**

Kermanshah University of Medical Sciences and Health Services

**Full name of responsible person**

Dr. Mahmoudreza Moradi

**Position**

Associate Professor, Pediatric Urologist

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences and Health Services

**Full name of responsible person**

Dr. Sina Ebrahimi

**Position**

Resident of Urology

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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*