

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of terazosin and tolterodine on ureterl stent related symptoms

Protocol summary

Summary

Ureteral stent (US) has been as essential tool in the urologist's surgeries and is useful instruments that its indications increase due to new stent technologies and improvement of patient's comfort. US associated with discomfort complications that include lower urinary tract symptoms (LUTS) as frequency, urgency, dysuria, incomplete emptying, flanks and suprapubic's pain, incontinence, hematuria, movement of stent, infection and encrustation of stent. US related symptoms are as same as LUTS due to benign prostate hyperplasia and overactive bladder which relieve with alpha-blockers and anticholinergic. The purpose of our study is to investigate the effect of terazosin(alfa blocker) and tolterodine(anticholinergic) lonely and together in comparison of placebo on US related symptoms. Our study will be done prospectively. The patients who underwent indwelling double-j stent distributed into four groups: 1)receive placebo 2)receive terazosin 2mg twice 3)receive tolterodine 2mg daily 4) receive terazosin 2mg twice and tolterodine 2mg daily. All of the patients receive prophylactic antibiotic and on demand analgesic. The patients will be used drugs from US indwelling to US removal time. After entrance to study, they fulfill the IPSS and VAS on the before indwelling US, two weeks after indwelling US and US removal time, then the investigators will evaluate the drug's effect on US related symptoms.

General information

Acronym

US= Ureteral stent IPSS= International Prostate Symptom Score LUTS= lower urinary tract symptom V

IRCT registration information

IRCT registration number: **IRCT201111255786N2**
Registration date: **2012-03-04, 1390/12/14**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-04, 1390/12/14

Registrant information

Name

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Name of organization / entity

Urmia University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences

Expected recruitment start date

2011-12-31, 1390/10/10

Expected recruitment end date

2012-12-27, 1391/10/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of terazosin and tolterodine on ureterl stent related symptoms

Public title

The effect of terazosin and tolterodine on ureterl stent related symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria: 1) Prior history of pelvic surgery 2)

Prior history of Transurethral Resection of the either Prostate or Bladder Tumor 3) Benign prostate hyperplasia 4) Recent or recurrent urinary tract infection 5) Chronic medication with α -blockers or Anti-cholinergic 6) Pregnancy 7) Prostatitis 8) Prostate cancer 9) Bilateral ureteroscopy or ureteral stenting 10) Age >18 and <55 11) Stone size >20 mm 12) Diabetes 13) Bladder Outlet Obstruction Inclusion criteria: If a patient dose not meet any exclusion criteria and to be undergone double-J stent indwelling.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

clinicaltrial.gov

Secondary trial Id

UUNRC 01

Registration date

2012-01-18, 1390/10/28

Ethics committees

1

Ethics committee

Name of ethics committee

Local ethic's committee of Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, Resalat Blvd, Urmia,Iran

City

Urmia

Postal code

Approval date

2011-12-03, 1390/09/12

Ethics committee reference number

p/4/2608

Health conditions studied

1

Description of health condition studied

Ureteral stent (Double-J stent) related symptoms

ICD-10 code

N20, N20.1

ICD-10 code description

Calculus of kidney, Calculus of ureter, Calculus of kidney with calculus of ureter, Hydronephrosis with ureteropelvic junction obstruction

Primary outcomes

1

Description

Lower Urinary Tract Symptoms

Timepoint

before intervention, 14days after intervention, stent removal time

Method of measurement

IPSS(International Prostate Symptom Score) and VAS(Visual Analogue Scale)

Secondary outcomes

1

Description

Drug complications

Timepoint

Stent removal time

Method of measurement

Getting history from patient

2

Description

Amount of analgesic consumption

Timepoint

Stent removal time

Method of measurement

Getting history from patient

Intervention groups

1

Description

Group1: Placebo same as tolterodine and terazosin dose

Category

Placebo

2

Description

Group2: Terazosin 2mg BID

Category

Treatment - Drugs

3

Description

Group3: Tolterodine 2mg Daily

Category

Treatment - Drugs

4

Description

Group4: Tolterodine 2mg Daily + Terazosin 2mg BID

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

Urology & Nephrology Research Center

Street address

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vicechancellor for research, Urmia University of Medical Sciences

Full name of responsible person

morteza motezaker

Street address

Urmia University of Medical Sciences, Resalat Blvd, Urmia,Iran

City

Urmia

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vicechancellor for research, Urmia University of Medical Sciences

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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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