Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of tolterodine on early irritative complication of lower urinary tract after transurethral resection of prostate

Protocol summary

Summary

Transurethral resection of prostate (TUR-P) is gold standard treatment of irritative and obstructive symptoms due to benign prostate hyperplasia (BPH). The most early complications after TUR-P (specially after catheter removal) are: urinary retention, and irritative symptoms such as frequency, dysuria, nucturia, and urgency that affects patients quality of life during the first weeks after TUR-P..In this trial we study the effects of toltrodin on patient's quality of life and early complications after TUR-P. This study is a double blind randomized placebo control clinical trials. Patients with indication of TUR-P surgery that hospitalized in Urmia imam Khomeini hospital during winter and spring 2012 are included. Exclusion criteria are: patients with urinary tract infection, bladder diverticule, neurologic or cardiovascular disease, hyperthyroidism, history of taking cholinergic or anti-cholinergic drugs, and post-voiding urinary residue more than 70ml. So 60 patients will randomized in treatment group (2mg toltrodine twice daily) and control group (placebo twice daily). After 1 month irritative lower urinary tract symptoms, pain (anti-analgesic usage) and patient's quality of life gather in two groups via questionnaire and conversation. Data will be analyzed by SPSS 17.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112255786N3**
Registration date: **2012-08-06, 1391/05/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-08-06, 1391/05/16

Registrant information

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Recruitment status

Recruitment complete

Funding source

Urmia university of medical sciences

Expected recruitment start date

2012-03-10, 1390/12/20

Expected recruitment end date

2012-06-09, 1391/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of tolterodine on early irritative complication of lower urinary tract after transurethral resection of prostate

Public title

Effects of tolterodine on early irritative complication of lower urinary tract after transurethral resection of prostate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: all patients that hospitalized for TURP in Feb to june in urmia imam khomeini hospital Exclusion

criteria: patients withbladder diverticula; neurologic disease; cardiovascular disease; hypo and hyperthyroidisim and patients with history of using cholinergic and antichonergic drugs, post-voding residue more than 70 ml

Age
From **50 years** old to **85 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **6**

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
Urmia university of medical sciences

Street address
Jahad street, urmia

City
Urmia

Postal code

Approval date
2011-12-19, 1390/09/28

Ethics committee reference number
4/2720 /پ

Health conditions studied

1

Description of health condition studied
Benign prostatic hyperplasia

ICD-10 code
D29.9

ICD-10 code description
N40

Primary outcomes

1

Description
Lower urinary tract symptoms

Timepoint
Before and one month after intervention

Method of measurement
Questionnaire

2

Description
analgesic nomber after surgery

Timepoint
1 month

Method of measurement
nomber of analgesic

3

Description
quality of life (IPSS)

Timepoint
1 month

Method of measurement
questionnaire

Secondary outcomes

1

Description
Urinary retension

Timepoint
1 month

Method of measurement
Questionnairy

Intervention groups

1

Description
tolteroadin 2mg ,oral tablet, 2 times daily

Category
Treatment - Drugs

2

Description
placebo, oral tablet, twice daily

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital
Full name of responsible person
Ali tehranchi
Street address
Ershad street, Urmia
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urmia university of medical sciences
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Jahad street
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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
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

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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