Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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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Name of organization / entity
Urmia University of Medical Sciences
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Iran (Islamic Republic of)
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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

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia university of medical sciences

Full name of responsible person

Morteza Motezaker

Street address

Jahad street

City

Urmia

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

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