Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparative study of tolterodine and diltiazem effects on OAB after prostatectomy

Protocol summary

Summary

This randomized double_blind clinical trial study will be done in evaluating the effect of diltiazem(an Antihypertensive drug) in treatment of post prostatectomy OAB. Men with the age of 65 to 85 undergone prostatectomy in the last month, suffering OAB right now after signing the agreement paper, enter the study.Patients with hypotension, heart failure, bradicardia and history of radiation therapy or BCG therapy will be excluded. We have 80 patients in two groups, first group gives diltiazem and second one takes tolterodine. Patients use one of the drugs for one month. Before prescription and one month after using the drug frequency, urgency and nocturia, will be documented based on International Prostate Symtom Score (I-PSS). At the end data will be processed in two groups by SPSS 16.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105096424N1**
Registration date: **2011-06-11, 1390/03/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-06-11, 1390/03/21

Registrant information

Name
Akbar Heidaripoor
Name of organization / entity
Kermanshah University of medical science
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Iran (Islamic Republic of)
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+98 83 1835 6469
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah university of medical science

Expected recruitment start date

2011-05-31, 1390/03/10

Expected recruitment end date

2012-05-30, 1391/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of tolterodine and diltiazem effects on OAB after prostatectomy

Public title

Diltiazem effects on overactive bladder syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients between 65 to 85 years old; with the history of prostatectomy in Emamreza Hospital; suffering OAB; agreement for enter to study. Exclusion criteria: Having systolic blood pressure under 90; bradicardia; congestive heart failure; bladder cancer; history of bladder radiation; interavesical BCG therapy.

Age

From **65 years** old to **85 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Kermanshah university of medical science

Street address

Shahidbeheshti boulevard

City

Kermanshah

Postal code

6714673159

Approval date

2011-03-14, 1389/12/23

Ethics committee reference number

2000308/420/7/پ

Health conditions studied

1

Description of health condition studied

Overactive bladder syndrome

ICD-10 code

n32.8

ICD-10 code description

other specified disorders of bladder

Primary outcomes

1

Description

Patients symptoms of OAB

Timepoint

First of trial and one month later

Method of measurement

Questions of patients

Secondary outcomes

1

Description

Side effects

Timepoint

First of trial and one month later

Method of measurement

Questions from patients

2

Description

Blood pressure

Timepoint

First of trial and one month later

Method of measurement

Blood pressure measurement mmhg

Intervention groups

1

Description

Intervention group gives 60mg diltiazem oral tablet twice daily for one month.

Category

Treatment - Drugs

2

Description

Control group gives 2mg tolterodine oral tablet twice daily for one month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emamreza Hospital

Full name of responsible person

Akbar Heidaripoor

Street address

Parastar boulevard

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, kermanshah university of medical science

Full name of responsible person

Dr. Reza Khodarahmi

Street address
Number2 building, Shahidbeheshti boulevard
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 science
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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Name of organization / entity
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Web page address

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