

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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, bradycardia 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 Symptom 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

Country

Iran (Islamic Republic of)

Phone

+98 83 1835 6469

Email address

dr.ak.heidaripoor@kums.ac.ir

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; bradycardia; congestive heart failure; bladder cancer; history of bladder radiation; interavesical BCG therapy.

Age

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

Gender

Male

Phase

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 Heidariipoor

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**Contact****Name of organization / entity**

Kermanshah university of medical science

Full name of responsible person

Akbar Heidaripoor

Position

Urology resident

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

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Medical Doctor

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

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Position

Urology resident

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

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City

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Postal code**Phone****Fax****Email****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