Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of effectivness of tamsulosin with and without minirin on lower urinary tract symptom of BPH in patient suitable for medical therapy

Protocol summary

Summary

Purpose : Comparison of effectiveness of tamsulosin combined with minirin and tamsulosin alone in treatment of BPH patients Inclusion and exclusion criteria : International prostatic symptom score more than 7 , 3 or more episodes of nocturia , abillity to providing time-urine volume chart were among the inclusion criteria . Surgical indication ,post voiding residue more than 200 cc , history of ischemic heart disease were the exclusion criteria . Method :354 patients with benign prostatic hyperplasia were randomized in to group A and B . Patients received tamsulosin plus minirin in group A and tamsulosin alone in group B . After 2 months , minirin was omitted from regimen of group A and added to regimen of group B .It continued for another 2 months . Patient were evaluated initially , 2 months and 4 months after study started respect to International Prostatic Symptom Score , nocturia , post voiding residue , peak flow rate , prostate volume , bladder wall thickness , nightly urine volume .Evaluations were done by sonography , uroflowmetry , time-voiding volume chart and International Prostatic Symptom Score questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205219819N1**
Registration date: **2012-06-18, 1391/03/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-06-18, 1391/03/29

Registrant information

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Mohammadreza Nowroozi

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Recruitment status

Recruitment complete

Funding source

Urology Research Center of Tehran University of Medical ScienceFerring company

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2013-12-01, 1392/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectivness of tamsulosin with and without minirin on lower urinary tract symptom of BPH in patient suitable for medical therapy

Public title

Effect of tamsulosin and minirin in treatment of BPH

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Filling consent form ; IPSS more than 7

; Nocturia more than 3 ; Ability of providing time-urinevolume chart Exclusion criteria : Not filling consent form ; Surgical indication ; History of ischemic heart disease ; Use of drugs like anti cholinergic , antisychotic , alpha blocker which can not be discontinued ; Contraindication to use tamsulosin and minirin ; If any side effect of drugs is present ; Cr more than 2 mg/dl ; PVR more than 200 cc

Age
No age limit

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **354**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciense

Street address
Qods st. , Keshavarz Blvd.

City
Tehran

Postal code

Approval date
2012-05-20, 1391/02/31

Ethics committee reference number
90/130/2843/د

Health conditions studied

1

Description of health condition studied
Benign Prostatic Hyperplasia

ICD-10 code
N 40

ICD-10 code description
Hyperplasia of prostate

Primary outcomes

1

Description
International prostatic symptom score

Timepoint
Before intervention - 2 mounth after intervention - 4 mounth after intervention

Method of measurement
International prostatic symptom score Questionaire

2

Description
nocturia

Timepoint
Before intervention - 2 mounth after intervention - 4 mounth after intervention

Method of measurement
IPSS questionaire

3

Description
nocturnal volume

Timepoint
Before intervention - 2 mounth after intervention - 4 mounth after intervention

Method of measurement
urine volume - time chart

4

Description
post voiding residue

Timepoint
Before intervention - 2 mounth after intervention - 4 mounth after intervention

Method of measurement
trans abdominal sonography

5

Description
prostate volume

Timepoint
Before intervention - 2 mounth after intervention - 4 mounth after intervention

Method of measurement
trans abdominal sonography

6

Description
bladder wall thickness

Timepoint
Before intervention - 2 mounth after intervention - 4 mounth after intervention

Method of measurement
trans abdominal sonography

7

Description
peak flow rate
Timepoint
Before intervention - 2 mounth after intervention - 4 mounth after intervention
Method of measurement
uroflowmetry

Secondary outcomes

1

Description
Hyponatremia
Timepoint
befor intervention - 2 days and 7 days after study started
Method of measurement
serum Na

Intervention groups

1

Description
Tamsulosin 0.4 mg daily for 2 episode of 2 mounths
Category
Treatment - Drugs

2

Description
Minirin 0.2 mg nightly for 2 mounth
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
UrologyResearch Center
Full name of responsible person
Gholam Reza Pourmand MD.
Street address
Sina Hospital , Imam Khomeini st.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
UrologyResearch Center
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
Tehran University of Medical Science
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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