

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparison of effectiveness 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 , ability 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

##### Name

Mohammadreza Nowroozi

##### Name of organization / entity

Tehran University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6119 2764

##### Email address

uorc@tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Urology Research Center of Tehran University of Medical Science  
Ferring 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 effectiveness 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-urine volume chart  
Exclusion criteria : Not filling consent form ; Surgical indication ; History of ischemic heart disease ; Use of drugs like anti cholinergic , antipsychotic , 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 Science

##### Street address

Qods st. , Keshavarz Blvd.

##### City

Tehran

##### Postal code

#### Approval date

2012-05-20, 1391/02/31

#### Ethics committee reference number

90/130/2843/3

## 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 month after intervention - 4 month after intervention

#### Method of measurement

International prostatic symptom score Questionnaire

### 2

#### Description

nocturia

#### Timepoint

Before intervention - 2 month after intervention - 4 month after intervention

#### Method of measurement

IPSS questionnaire

### 3

#### Description

nocturnal volume

#### Timepoint

Before intervention - 2 month after intervention - 4 month after intervention

#### Method of measurement

urine volume - time chart

### 4

#### Description

post voiding residue

#### Timepoint

Before intervention - 2 month after intervention - 4 month after intervention

#### Method of measurement

trans abdominal sonography

### 5

#### Description

prostate volume

#### Timepoint

Before intervention - 2 month after intervention - 4 month after intervention

#### Method of measurement

trans abdominal sonography

### 6

#### Description

bladder wall thickness

#### Timepoint

Before intervention - 2 month after intervention - 4 month after intervention

#### Method of measurement

trans abdominal sonography

## 7

### Description

peak flow rate

### Timepoint

Before intervention - 2 month after intervention - 4 month after intervention

### Method of measurement

uroflowmetry

## Secondary outcomes

### 1

### Description

Hyponatremia

### Timepoint

before 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 months

### Category

Treatment - Drugs

### 2

### Description

Minirin 0.2 mg nightly for 2 month

### 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

#### Full name of responsible person

Mohammad Reza Nowroozi MD.

#### Position

Associated professor of urology

#### Other areas of specialty/work

#### Street address

Qods st , Keshavarz Blvd.

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#### Email

mrnowroozi@yahoo.com

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www.tums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Science

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Assosiated professor of urulogy

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**Web page address**

## Person responsible for updating data

### 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*