

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Comparison of oral tamsulosin with oral tamsulosin and oral isosorbide dinitrate with in improvements trial without catheter (TWOC) for patients with acute urinary retention due to benign prostatic hyperplasia (BPH)

#### Protocol summary

##### Summary

This study is a clinical trial which performs in emergency department of Imam Khomeini hospital in Sari. All patients are under urinary catheter. After that they were explained about doing this research, written informed consent will be taken from them to enter into the study .and then, the samples are divided into two groups of 38 members. The first group received 0/4 mg of Tamsulosin Capsule from Modava daroo Company; it is given once a day at bed time. The second group received 0/4 mg of Tamsulosin hydrochloride along with Isosorbide dinitrate slow release by 20 mg every 12 hours and then the patient discharge from the Emergency department by doing urine and kidney function tests. After 72 hours of taking medication, the patients are reexamined again and their urinary catheter is removed, and the ability to urinate without a catheter is evaluated and weekly follow up will continue for a month and prostate volume verified by transrectal ultrasonography, and reuse of these patients to urinary catheter is checked. All patients 's information will be by the executive through track information which includes First and last name , Case number, Admission date , underlying disease , consumable drudges , Sonographic finding, Prostate volume, Urea, Creatine , Urine test, distended bladder, hypogasteric pain, urination feel, Age, the amount of urine discharged , will be gathered .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017041724606N3**  
Registration date: **2017-05-10, 1396/02/20**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-05-10, 1396/02/20

##### Registrant information

###### Name

Hamed Aminiahidashti

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3336 1700

###### Email address

h.aminiahidashti@mazums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for researche, Mazandaran University of Medical Siences

##### Expected recruitment start date

2016-11-21, 1395/09/01

##### Expected recruitment end date

2018-01-21, 1396/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of oral tamsulosin with oral tamsulosin and oral isosorbide dinitrate with in improvements trial without catheter (TWOC) for patients with acute urinary retention due to benign prostatic hyperplasia (BPH)

##### Public title

Comparison of oral tamsulosin with oral tamsulosin and

oral isosorbide dinitrate with in improvements trial without catheter (TWOC) for patients with acute urinary retention due to benign prostatic hyperplasia (BPH)

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria: patients with acute urinary retention caused by benign prostatic hypertrophy(BPH). Exclusion criteria: end stage renal disease; diabetes; history of urinary system surgery; malignancy; contraindication of tamsulosin and isosorbide consumption.

#### **Age**

From **40 years** old

#### **Gender**

Male

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **76**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single 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 of Mazandaran University of Medical Sciences

###### **Street address**

Mazandaran University of Medical Sciences, Jooybar treeway, Imam Square

###### **City**

Sari

###### **Postal code**

4815724971

##### **Approval date**

2016-10-17, 1395/07/26

##### **Ethics committee reference number**

IR.MAZUMS.IMAMHOSPITAL.REC.95.2440

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Acute urinary retention

##### **ICD-10 code**

R33

##### **ICD-10 code description**

Retention of urine

### **Primary outcomes**

#### **1**

##### **Description**

Try of urination without a catheter(TWOC)

##### **Timepoint**

72 hours after intervention

##### **Method of measurement**

Observe of urination without a catheter(TWOC)

### **Secondary outcomes**

#### **1**

##### **Description**

Vertigo

##### **Timepoint**

72 hours after intervention

##### **Method of measurement**

Observation

#### **2**

##### **Description**

Blood pressure

##### **Timepoint**

72 hours after intervention

##### **Method of measurement**

Sphygmomanometer(mmHg)

### **Intervention groups**

#### **1**

##### **Description**

The control group tamsulosin capsules (0.4 mg) of the drug treatment is given once a day at bedtime in 3 days

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Intervention group Tamsulosin hydrochloride capsules (0.4mg) of Medavadarv once a day at bedtime in 3 days, with slow-release tablets of ISO Surbid Di nitrite 20mg every 12 hours in 3 days

##### **Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Emam Khomeini Hospital

**Full name of responsible person**

Hamed Aminiahidashti

**Street address**

Amir mazandarani Bolivard

**City**

Sari

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for researche, Mazandaran University of Medical Siences

**Full name of responsible person**

Ahmadali Enayati

**Street address**

Vice chancellor for researche, Mazandaran University of Medical Siences, Moallem Square

**City**

Sari

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for researche, Mazandaran University of Medical Siences

**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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Hamed Aminiahidashti

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

Emergency Department, Imam Khomeini Hospital, Amirmazandarani avenue

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hamedaminiahidashti@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

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Mazandaran University of Medical Sciences

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**Position**

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**Other areas of specialty/work**

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## Person responsible for updating data

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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*