

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Hamed Aminiahidashti

Position

Assistant Professor

Other areas of specialty/work

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Assistant Professor

Other areas of specialty/work

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Fax

Email

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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