Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of magnesium hydroxide and tamsulosin with tamsulosin alone on urinary symptoms in patients with benign prostatic hyperplasia

Protocol summary

Study aim

The effect of magnesium hydroxide on urinary symptoms caused by benign prostatic hyperplasia

Design

This was a Phase 3, double blind clinical trial study. Patients and researcher were kept blind. The sample size was 96. Based on quadruple blocks, sample allocation was performed. We named the intervention group "A" and the control group "B". Blocks were numbered according to the random number table. 49 patients were in the intervention group and 47 patients were in the control group.

Settings and conduct

Patients with benign prostatic hypertrophy referring to Imam Hossein Shahroud Hospital

Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1-Patients aged 55 to 75 with benign prostatic hyperplasia and referring to Imam Hossein Shahroud Hospital 2-Patients Without Absolute Surgery Indication 3-Patients without benign prostatic hyperplasia treatment Exit criteria Study: 1- Diabetics 2-Patients with discopathy or other neurological diseases that affect the bladder and prostate, and rectum 3- All patients with a history of lower urinary system surgery 4-Patients with a history of neurological anorectal disease 5- Complications of drugs and laxatives, such as diarrhea, etc 6-Smokers and opium users

Intervention groups

Intervention group: Magnesium hydroxide 8% is the main intervention and is administered at a dose of 30 cc per night, and Tamsulosin capsules are given at a dose of 0.4 mg overnight. control group: All people receive only Tamsulosin capsules, 0.4 mg, every night.

Main outcome variables

Feeling bladder drainage; Repetitive urination in less than 2 hours of bladder emptying; Urinary flow rate; Need for pressure to empty the bladder; Urinary frequency during sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180115038379N1**
Registration date: **2018-04-09, 1397/01/20**
Registration timing: **retrospective**

Last update: **2018-04-09, 1397/01/20**
Update count: **0**

Registration date

2018-04-09, 1397/01/20

Registrant information

Name

Hamed Dashani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3871 2162

Email address

dashani.h@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-02-07, 1396/11/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of magnesium hydroxide and tamsulosin with tamsulosin alone on urinary symptoms in patients with benign prostatic hyperplasia

Public title
The effect of magnesium hydroxide on urinary symptoms caused by benign prostatic hyperplasia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients at the age of 55-75 years with benign prostatic hyperplasia referred to Imam Hossein Shahroud Hospital Patients who do not have an absolute indication of surgery Patients who have not received the drug for the treatment of benign prostatic hyperplasia
Exclusion criteria:
diabetic patients Patients with discopathy or other neurological diseases involving the bladder, prostate, anus and rectum All patients with a history of lower urinary tract surgery Patients with anorexia nervosa history Complications following drug and laxative consumption Smokers and opium users
Age
From **55 years** old to **75 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **96**
Actual sample size reached: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Sample allocation was performed through block randomization (quadruple blocks). We named the intervention group "A" and the control group "B". Blocks were numbered using random numbers derived from random number table. The entry of individuals into each group was done based on the selected block' number. 49 patients were placed in the intervention group and 47 patients were placed in the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double-blind clinical trial and will be blind to researchers (observers) and patients (subjects)
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahroud University of Medical Sciences
Street address
next to Haft Tir Square., Shahroud., iran
City
Shahroud
Province
Semnan
Postal code
36147-73947
Approval date
2016-02-23, 1394/12/04
Ethics committee reference number
IR.SHMU.REC.1394.203

Health conditions studied

1

Description of health condition studied
Benign prostate hyperplasia
ICD-10 code
D29.1
ICD-10 code description

Primary outcomes

1

Description
Feeling bladder emptying
Timepoint
Before treatment and 13 weeks after treatment
Method of measurement
Prostate symptom scoring questionnaire

2

Description
Repetitive urination in less than 2 hours of bladder emptying
Timepoint
Before treatment and 13 weeks after treatment
Method of measurement
Prostate symptom scoring questionnaire

3

Description
Urinary flow rate
Timepoint
Before treatment and 13 weeks after treatment
Method of measurement
Prostate symptom scoring questionnaire

4

Description
Need for pressure to empty the bladder
Timepoint
Before treatment and 13 weeks after treatment
Method of measurement
Prostate symptom scoring questionnaire

5

Description
Urinary frequency during sleep
Timepoint
Before treatment and 13 weeks after treatment
Method of measurement
Prostate symptom scoring questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Magnesium hydroxide 8% is the main intervention and is administered at a dose of 30 cc per night, and tamsulosin capsules are given at a dose of 0.4 mg overnight.
Category
Treatment - Drugs

2

Description
Control group: All people receive only tamsulosin capsule, 0.4 mg, every night
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Training and Therapy Hospital in Shahrood
Full name of responsible person
Hamed dashani
Street address
Imam Hossein Hospital., Imam Hossein Square., Imam Street., Shahroud
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36147-73947
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Dashani.h@shmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Mohammad Hassan Emamian
Street address
Shahroud University of Medical Sciences Research & Technology., Haft Tir Square.,Shahroud.,Iran
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emamian@shmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Naser Mogharabian
Position
Urologist
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available