

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

the Effectiveness of Different Tamsulosin Doses on Lower Urinary Tract Symptoms in Patients with Benign Prostatic Hyperplasia

Protocol summary

Study aim

The effectiveness of Different Tamsulosin Doses on Lower Urinary Tract Symptoms in Patients with Benign Prostatic Hyperplasia

Design

A single-blind clinical trial with two interventional groups that using a 0.4 mg tamsulosin capsule in first group and a 0.8 mg tamsulosin capsule in second groups. This clinical trial randomized with random-numbered table.

Settings and conduct

Of the patients will come with lower urinary tract symptoms to the Imam Hasan Hospital and have inclusion criteria sampling will be done. Patients will be placed randomly in two groups. Patients in the first group will be received a 0.4 mg tamsulosin capsule and the patients in the second group will be received a 0.8 mg tamsulosin capsule. Patients will be evaluated before and after the drug consumption based on IPSS. Second evaluation will be done after 8 weeks of using the drug. Finally, data collection and analysis will be done and thus we will examine the efficacy of different Tamsulosin doses.

Participants/Inclusion and exclusion criteria

Having consent for entry to study IPSS over 20 No history of prostate surgery No history of Tamsulosin consumption No significant kidney disease

Intervention groups

1. A group that will be received a 0.4 mg tamsulosin capsule. 2. A group that will be received a 0.4 mg tamsulosin capsule.

Main outcome variables

International Prostate Symptom Score (IPSS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160514027893N3**

Registration date: **2019-04-12, 1398/01/23**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-12, 1398/01/23**

Update count: **0**

Registration date

2019-04-12, 1398/01/23

Registrant information

Name

Ramin Haghighi

Name of organization / entity

North Khorasan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 58 3272 4475

Email address

haghighi.ramin@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the Effectiveness of Different Tamsulosin Doses on Lower Urinary Tract Symptoms in Patients with Benign Prostatic Hyperplasia

Public title

Effect of Tamsulosin on Prostate

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients with LUTS (Lower Urinary Tract Symptoms) who need tamsulosin drug and are satisfied.
Exclusion criteria:
having prostat surgery history tamsulosin consumption history unsatisfication

Age
No age limit

Gender
Male

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to two groups of intervention 1and 2 by random number table.

Blinding (investigator's opinion)
Single blinded

Blinding description
After selecting and randomizing, patients will be divided into two groups. Patients will not know how to group in groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of North Khorasan University of Medical Sciences
Street address
Medical School.Shahriar Ave
City
Bojnord
Province
North Khorasan
Postal code
9453155174
Approval date
2018-11-27, 1397/09/06
Ethics committee reference number

IR.nkums.rec.1397.076

Health conditions studied

1

Description of health condition studied

Benign prostatic hyperplasia

ICD-10 code

N40

ICD-10 code description

Hyperplasia of prostate

Primary outcomes

1

Description

Reducing the amount of international prostate symptom score (IPSS)

Timepoint

Measuring IPSS at the beginning of the study (before the intervention) And 8 weeks after the start of taking tamsulosin capsules

Method of measurement

International prostate symptom score (IPSS)

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: .A group that will be received a 0.4 mg tamsulosin capsule of Behestan Pharmaceutical Company once a day for 8 weeks.

Category

Treatment - Drugs

2

Description

Second intervention group: A group that will be received a 0.8 mg tamsulosin capsule of Behesatn Pharmaceutical Company once a day for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hasan Hospital

Full name of responsible person

Ramin Haghighi

Street address

Esfarayan Road, 4 km of Arkan, Imam Hasan Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bojnourd 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
Bojnourd University of Medical Sciences
Full name of responsible person
Ahmad Kameli
Position
Instructor
Latest degree
Master

Other areas of specialty/work

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Person responsible for updating data

Contact

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Student
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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available