Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 tamosulosin capsule in first group and a 0.8 mg tamosulosin capsule in second groups.This clinical trial randomized whit 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 recieved a 0.4 mg tamosulosin capsule and the pationts in the second group will be recieved a 0.8 mg tamosulosin 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 Tamsolusin 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 recieved a 0.4 mg tamosulosin capsule. 2. A group that will be recieved a 0.4 mg tamosulosin 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

Esfarayen Road, 4 km of Arkan, Imam Hasan Hospital

City
Bojnord
Province
North Khorasan
Postal code
9453155174
Phone
+98 58 3222 1910
Email
info@nkums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Amirhosein Khoshi
Street address
Esfarayen Road, 4 km of Arkan, Imam Hasan Hospital
City
Bojnord
Province
North Khorasan
Postal code
9453155174
Phone
+98 58 3229 7096
Email
ah.khoshi@nkums.ac.ir
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
Medical Education
Street address
Shahriar Ave, School of Nursing and Midwifery
City
Bojnord
Province
North Khorasan
Postal code
9453155174
Phone
+98 58 3222 1910
Email
ahmad_kamely@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Ramin Haghighi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Urology
Street address
Esfarayen Road, 4 km of Arkan, Imam Hasan Hospital
City
Bojnord
Province
North Khorasan
Postal code
9453155174
Phone
+98 58 3222 1910
Email
haghighi.ramin@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Hossein Bavandy
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Nursery
Street address
Esfarayen Road, 4 km of Arkan, Imam Hasan Hospital
City
Bojnord
Province
North Khorasan
Postal code

9453155174

Phone

+98 58 3228 9294

Email

hossein.bavandi@yahoo.com

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