

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Determining and comparing the effectiveness of tadalafil and tamsulosin on the control of bladder neck obstruction symptoms in patients with benign prostatic hyperplasia.

Protocol summary

Study aim

What will be done in the present Babylonian interventional study is to evaluate and compare the effectiveness of two drug classes in this category, including tadalafil and tamsulosin, in removing the blockage caused by BPH.

Design

A non-randomized clinical trial study without blinding with parallel groups on 48 patients who were divided into two groups of 24 people in such a way that in one group tadalafil with a dose of 5 mg once a day and in the second group tamsulosin with a dose of 0.4 mg daily both for A period of two months is prescribed for patients. Both categories of drugs are taken half an hour after dinner. After two months of taking the drugs, the patients should be examined for obstructive symptoms and bladder neck stricture through urodynamic analysis, cystourethroscopy and IPSS.

Settings and conduct

Tehran Islamic Azad University Hospitals

Participants/Inclusion and exclusion criteria

Suffering from BPH, suffering from complications of BPH progression in the form of bladder neck obstruction

Intervention groups

First intervention group: receiving tadalafil The second intervention group: receiving tamsulosin

Main outcome variables

type of medicine Age The duration of the onset of symptoms of the disease Bladder neck obstruction Age of the patient Side effect

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230628058608N1**

Registration date: **2023-09-25, 1402/07/03**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-25, 1402/07/03**

Update count: **0**

Registration date

2023-09-25, 1402/07/03

Registrant information

Name

Sara Negintaji zardak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 917 941 9867

Email address

negintaji.sara@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-21, 1402/03/31

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining and comparing the effectiveness of tadalafil and tamsulosin on the control of bladder neck obstruction symptoms in patients with benign prostatic hyperplasia.

Public title

Comparing the effectiveness of tadalafil and tamsulosin on the control of bladder neck obstruction symptoms in patients with benign prostatic hyperplasia.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from BPH, suffering from complications of BPH progression in the form of bladder neck obstruction

Exclusion criteria:

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 48

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not 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 Islamic Azad University

Street address

Dr. Shariati Street., Shahid Khaghani Street
(Zargandeh)

City

Tehran

Province

Tehran

Postal code

1918938136

Approval date

2022-12-25, 1401/10/04

Ethics committee reference number

ir.iau.tmu.rec.1401.326

Health conditions studied

1

Description of health condition studied

Suffering from BPH, suffering from complications of BPH progression in the form of bladder neck obstruction

ICD-10 code

N40

ICD-10 code description

Enlarged prostate

Primary outcomes

1

Description

Determining and comparing the recovery rate of bladder neck obstruction symptoms in the group treated with tadalafil and tamsulosin based on age

Timepoint

Within two months

Method of measurement

IPSS

Secondary outcomes

1

Description

Bladder neck obstruction-prostate irritation symptoms

Timepoint

Within 2 months

Method of measurement

IPSS

Intervention groups

1

Description

The first intervention group: receiving tadalafil, tadalafil is prescribed to patients at a dose of 5 mg once a day for two months and half an hour after dinner. Tadalafil belongs to a group of drugs called phosphodiesterase type 5 (PDE5) inhibitors and is sold under the brand name Cialis in packs of 30 by Medipharma.

Category

Treatment - Drugs

2

Description

The second intervention group: receiving tamsulosin, tamsulosin at a dose of 0.4 mg once a day for a period of two months and half an hour after dinner is prescribed to the patients. Tamsulosin belongs to a group of drugs called phosphodiesterase type 5 (PDE5) inhibitors, and it is supplied with a dose of 0.4 mg in 30-packs by the Iranian pharmaceutical company Galinos.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals, Islamic Azad University of Tehran

Full name of responsible person

Dr. Ali Reza Nouri

Street address

Shariati, Zargandeh., South Attari Moghadam

City

Tehran

Province

Tehran

Postal code

1916893813

Phone

+98 21 2200 6660

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iautmu@iautmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

University of Medical Sciences

Street address

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Phone

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Fax**Email**

iautmu@iautmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

sara negintaji zardak

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Ali Reza Nouri

Position

University professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ali Reza Noori

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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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