

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Sildenafil and Tadalafil in the treatment of benign prostatic hyperplasia

Protocol summary

Study aim

Comparison of the efficiency of Tadalafil with Sildenafil in the treatment of benign prostatic hyperplasia (BPH) based on changes in International Prostate Symptom Score (IPSS) and Post Void Residue (PVR) before and after treatment with each of the drugs and assessing the possible role of patients age and initial prostate size in responsiveness to therapy.

Design

A multi-center, randomized, single-arm study in 66 patients; enrolled between December 2020 and April 2021

Settings and conduct

66 patients with benign prostatic hyperplasia (BPH), who were referred to 3 referral hospitals will be chosen by simple random sampling. firstly; each patient will be treated with 50 milligrams of sildenafil for 6 week; secondly, they will undergo a 4 week washout period and lastly, they will be treated with 5 milligrams of tadalafil for 6 weeks. in each appointment International prostate symptom score (IPSS) and post-void residue (PVR) will be recorded the changes in IPSS and PVR will be evaluated statistically.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: having benign prostatic hyperplasia and not being treated with other drugs in the last month and exclusion criteria are: unwillingness to participate; concurrent treatment with nitrates; past medical history of cardiac diseases, hypotension, prostate surgery, lumbar discopathy or surgery, extensive surgeries of the pelvis and perineum, concurrent neurogenic bladder and active urinary tract infection.

Intervention groups

All patients will be treated with the same agents; firstly, each patient will be treated with 50 milligrams of sildenafil for 6 week; secondly, they will undergo a 4 week washout period and lastly, they will be treated with 5 milligrams of tadalafil for 6 weeks.

Main outcome variables

post-void residue ; International prostate symptom score , Initial prostate size, age

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210925052576N1**

Registration date: **2021-10-07, 1400/07/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-07, 1400/07/15**

Update count: **0**

Registration date

2021-10-07, 1400/07/15

Registrant information

Name

Mazyar Zahir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2291 1268

Email address

mazyar1995@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-02, 1400/07/10

Expected recruitment end date

2021-11-01, 1400/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Sildenafil and Tadalafil in the treatment of benign prostatic hyperplasia

Public title

Comparison of Sildenafil and Tadalafil in the treatment of benign prostatic hyperplasia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosed with Benign Prostatic Hyperplasia (BPH) with lower urinary tract symptoms(LUTS) No prior history of other treatments in last month

Exclusion criteria:

Unwilling to take part in the study Concurrent treatment with Nitrates History of cardiac diseases or hypotension History of prostate surgery History of Lumbar discopathy or prior herniated disc surgery History of extensive pelvic or perineal surgeries Being a known case of neurogenic bladder or presence of its symptoms Having an active urinary tract infection (UTI)

Age

No age limit

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 66

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features

This study is uniquely designed as a single arm study with two consecutive interventions; each patient will be treated with Sildenafil for 6 weeks, then going through a 4 week washout period and lastly, they will be treated with Tadalafil for 6 weeks. The effectiveness of these regiments will be evaluated separately on each patient. Previous studies have shown that prostate size prior to treatment for BPH, profoundly affects the outcome of therapy; therefore, in order to eliminate this confounding factor; every patient will take both drug interventions in consecutive, separate stages and the results will be compared in order to establish the superior treatment choice.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Islamic Azad University Tehran Medical Unit

Street address

Gol-e-Yakh st, Ayeene blvd, Amir-pa-barja st, Shariati st, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1949635881

Approval date

2021-01-04, 1399/10/15

Ethics committee reference number

IR.IAU.TMU.REC.1399.339

Health conditions studied**1****Description of health condition studied**

Benign prostatic hyperplasia (BPH)

ICD-10 code

N40.1

ICD-10 code description

Enlarged prostate with lower urinary tract symptoms

Primary outcomes**1****Description**

Post-void residue (PVR)

Timepoint

Measurement of post-void residue on first appointment(before treatment with sildenafil) and after 6 weeks (after treatment with sildenafil), 10 weeks(after washout period and before treatment with tadalafil) and 16 weeks(after treatment with tadalafil)

Method of measurement

Bladder ultrasonography

2**Description**

International Prostate Symptom Score (IPSS)

Timepoint

Calculation of International Prostate Symptom Score(IPSS) on first appointment(before treatment with sildenafil) and after 6 weeks (after treatment with sildenafil), 10 weeks(after washout period and before treatment with tadalafil) and 16 weeks(after treatment

with tadalafil)

Method of measurement

IPSS questionnaire

3

Description

Initial prostate size

Timepoint

prior to treatment

Method of measurement

prostate ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (first stage) : 50 milligram sildenafil tablet, nightly, for 6 weeks

Category

Treatment - Drugs

2

Description

Intervention group(second stage) : 5 milligram tadalafil tablet, nightly, for 6 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farhikhtegan hospital

Full name of responsible person

Hamidreza Gholamrezayi

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farhikhteganhospital@gmail.com

2

Recruitment center

Name of recruitment center

Milad hospital

Full name of responsible person

Farhad Hamzezadeh

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adjunct to Milad tower, Hemmat highway, Tehran, Iran

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3

Recruitment center

Name of recruitment center

Amir-Almomenin hospital

Full name of responsible person

Nasser Rahbar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

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?

No
Title of funding source
hospital facilities
Proportion provided by this source
5
Public or private sector
Private
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
Mazyar Zahir
Position
Medical Intern
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

all data is shareable after undergoing a anonymity procedure with removal of patients name and surname.

When the data will become available and for how long

available from september 2022

To whom data/document is available

medical researchers

Under which criteria data/document could be used

descriptive analysis is permitted.

From where data/document is obtainable

email to: mazyar1995@gmail.com

What processes are involved for a request to access data/document

evaluation of the resume of the researcher who have asked for the data and emailing the files to them after making sure of their prior experience in medical research.

Comments