Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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 Sildenafal 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
Street address
Shohadaye Hesarak Blvd, Simon bolivar Blvd, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1477899679
Phone
+98 21 4486 7252
Email
farhikhteganhospital@gmail.com

2

Recruitment center
Name of recruitment center
Milad hosptital
Full name of responsible person
Farhad Hamzezadeh
Street address
adjunct to Milad tower, Hemmat highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614531
Phone
+98 21 82039
Email
miladhospital@gmail.com

3

Recruitment center
Name of recruitment center
Amir-Almomenin hospital
Full name of responsible person
Nasser Rahbar
Street address
Shirmohamadi st, Nazi-abad, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1811694784
Phone
+98 21 5534 6550
Email
amhos@iautmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Farshad Hashemian
Street address
Gole-yakh st, Ayeene blvd, Amir-pa-barja st, Shariati st, Tehran
City
Tehran
Province
Tehran
Postal code
1949635881
Phone
+98 21 2660 2642
Email
info@park.iau.ir
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
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
Shohadaye Hesarak Blvd, Simon bolivar Blvd, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1477899679

Phone
+98 21 4486 7262

Fax

Email
mazyar1995@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Mohammad Samzade

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Urology

Street address
Shohadaye Hesarak Blvd, Simon bolivar Blvd, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1477899679

Phone
+98 21 4486 7262

Email
o_samzadeh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Mazyar Zahir

Position
Medical Intern

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
Shohadaye Hesarak Blvd, Simon bolivar Blvd, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1477899679

Phone
+98 21 4486 7262

Fax

Email
mazyar1995@gmail.com

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