Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative efficacy assessment of Tamsulosin vs. Tamsulosin plus Pentoxifylline in the treatment of LUTS/BPH in two 30 persons groups of patients: A preliminary study

Protocol summary

Study aim

To determine and compare the efficacy assessment of Tamsulosin plus Pentoxifylline Vs Tamsulosin in the treatment of Lower urinary tract symptoms (LUTS) of Benign prostate hyperplasia(BPH)

Design

The clinical trial has a control group and a parallel group that is double-blinded. The total volume of the study is 60 people who are divided randomly into two groups of 30 people.

Settings and conduct

This study was conducted in Shahid Motahari Clinic in Shiraz and the patients and the person who delivers the drugs to patients have been blinded and do not know whether pentoxifylline is prescribed or Placebo. At the beginning of the work, the patient will be taken a complete history and the amount of blood pressure, creatinine, PSA and prostate volume will be evaluated and if he had the necessary conditions about the existing study and the possibility of participating in it for the patient, and if the patient's consent after obtaining written consent from him, he would be entered and the necessary variables will be evaluated before the beginning of treatment and 12 weeks after the start of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age>40, Prostate volume>20ml, creatinine<2, maximum urinary flow rate<15ml/s, Voide volume>100ml, International Prostate Symptom Score>13 Exclusion criteria: Age<40, Previous prostate surgery, History of prostate cancer, Renal dysfunction, History of severe liver impairment, Severe cardiovascular diseases, Active Urinary tract infection, Bladder calculus, Exposure to sex hormone within 3 months prior, History of neurogenic bladder, History of urethral stricture, Severe hypotension, Postvoid residual urine volume of > 250 ml

Intervention groups

Administration of pentoxifylline and tamsulosin in men with Lower urinary tract symptoms (LUTS) of Benign prostate hyperplasia(BPH)

Main outcome variables

International Prostate Symptom Score Quality of Life Maximum urinary flow rate Voided volume

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210729052012N1**
Registration date: **2022-01-20, 1400/10/30**
Registration timing: **prospective**

Last update: **2022-01-20, 1400/10/30**
Update count: **0**

Registration date

2022-01-20, 1400/10/30

Registrant information

Name

Alireza Dehghanmanshadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3820 6907

Email address

alireza.dehghan68@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-04, 1400/11/15

Expected recruitment end date
2022-06-05, 1401/03/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative efficacy assessment of Tamsulosin vs. Tamsulosin plus Pentoxifylline in the treatment of LUTS/BPH in two 30 persons groups of patients: A preliminary study

Public title
Comparative efficacy assessment of Tamsulosin vs. Tamsulosin plus Pentoxifylline in the treatment of LUTS/BPH: A preliminary study
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age>40 International Prostate Symptom Score(IPSS)>13 Prostate Volume>20ml maximum urinary flow rate(Qmax)<15ml/s Voided Volume>100ml creatinine(Cr)<2
Exclusion criteria:
Age<40 history of prostate cancer renal dysfunction previous prostate surgery bladder calculus active UTI postvoid residual urine volume of > 250 mL exposure to sex hormone within 3 months prior history of severe liver impairment history of severe cardiovascular diseases severe hypotension history of neurogenic bladder history of urethral stricture
Age
From **40 years** old
Gender
Male

Phase
4
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible patients after first visit, will be devide in two groups with randomizer by third party
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding is done so that in the group receiving Pentoxyfilline, this pill is powdered and poured into the capsules and delivered to the patients and in the group that should only receive Tamsulosin, In addition to Tamsulosin, placebo is given.Placebo so that starch is poured into the capsules and packed and delivered to the patients And finally, the patient doesn't know if he's using pentoxyfilline or placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
University of Medical Sciences building, near Helal Ahmar, Zand street
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2020-08-03, 1399/05/13
Ethics committee reference number
IR.SUMS.MED.REC.1399.261

Health conditions studied

1

Description of health condition studied
Benign Prostate Hyperplasia
ICD-10 code
N40.1
ICD-10 code description
Enlarged prostate with lower urinary tract symptoms

Primary outcomes

1

Description
International Prostate Symptom Score
Timepoint
At the beginning of the study and 12 weeks after treatment
Method of measurement
International Prostate Symptom Score chart

2

Description
Quality of Life
Timepoint
At the beginning of the study and 12 weeks after

treatment

Method of measurement

Quality of life due to urinary symptoms chart

3

Description

Maximum urinary flow rate

Timepoint

At the beginning of the study and 12 weeks after treatment

Method of measurement

Uroflowmetry

4

Description

Voided volume

Timepoint

At the beginning of the study and 12 weeks after treatment

Method of measurement

Uroflowmetry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tamsulosin 0.4mg everyday and Pentoxyfilline 400mg every 8 hour in 12 weeks were given.

Category

Treatment - Drugs

2

Description

Control group: Tamsulosin 0.4mg everyday and placebo every 8 hour in 12 weeks were given.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Clinic

Full name of responsible person

Soroush Sadr

Street address

Shahid Motahari Clinic, Namazi Sq

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Alireza Dehghanmanshadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact
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Professor
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Person responsible for updating data

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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
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Study Statistical Data- The entire data of individuals can be shared after people are identifiable.
When the data will become available and for how long
Start accessing 6 months after the results are printed
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Certain conditions are not required.
From where data/document is obtainable
Alireza Dehghanmanshadi Email: alireza.dehghan68@gmail.com
What processes are involved for a request to access data/document
The applicant sends his request via email and after reviewing the request and confirming it, the documents will be obtained within about a month.
Comments