Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

The Efficacy and side effects of different doses of finastride/ dutastride accompanying with tamsulosin for Benign prostate hyperplasia in Iranian men

Protocol summary

Study aim

1- the comparison of QMAX(maximal flow rate) ,IPSS SCORE(international prostate symptom score) ,SDI SCORE(sexual desire inventory),IIEF15(international index of erectile function) before, 3 and 6 months after treatment in each group and between five groups in this study

Design

randomized ,parallel group trial with blinded outcome assessment .Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site

Settings and conduct

this study is performed by urology research center in shahid beheshti university of medical sciences.This study include 5 groups .group one is considered as a control group .The finastride 5mg and 3mg , dutastride 0.5mg and 0.25mg and placebo tablets are identical in appearance and prepared by tansnim company. QMAX , IPSS score , IIEF15 score, SDI score are assessed before , 3 and six months after treatment . the complication of drug was assessed in each group .investigator, care provider, patients, data analyzer , outcome assessor were all blinded .

Participants/Inclusion and exclusion criteria

inclusion criteria :prostate size larger than 30 cc, moderate to sever IPSS score . exclusion criteria: PSA more than 4 ng/dl., history of bladder or prostate cancer, history of prostate surgery, history of urethral stricture

Intervention groups

group one take tamsulosin 0.4mg once daily and placebo ,group 2 take tamsulosin 0.4mg daily and finasteride 5mg once daily , group 3 take one capsule of tamsulosin 0.4mg and finasteride 3mg once daily , group 4 take one capsule of tamsulosin 0.4mg and dutastride 0.25mg once daily , group 5 take one capsule of tamsulosin 0.4mg and dutastride 0.5mg once daily .

Main outcome variables

QMax, IPSS SCORE .IIEF15 SCORE . SDI SCORE

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120516009772N2**
Registration date: **2021-01-18, 1399/10/29**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-18, 1399/10/29**
Update count: **0**

Registration date

2021-01-18, 1399/10/29

Registrant information

Name
amir reza abedi
Name of organization / entity
urology research center
Country
Iran (Islamic Republic of)
Phone
+98 21 2230 7520
Email address
arabedi_80@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Efficacy and side effects of different doses of finastride/ dutastride accompanying with tamsulosin for Benign prostate hyperplasia in Iranian men

Public title
Effect of finastride/ dutastride accompanying with tamsulosin in treatment of Benign prostate hyperplasia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
prostate size larger than 30 gram moderate to sever symptom (ipss>13) older than 55 years old Qmax of 4–15 mL/s from a pre-void bladder volume ≥150 and ≤550 mL (minimum voided volume 125 mL) with >6 months history of BPH-LUTS
Exclusion criteria:
no surgical indication(bladder stone,uremia,urinary retention,gross hematuria,recurrent infection) no previous prostate surgery no urethral stricture PSA>4 history of severe renal or hepatic insufficiency History of bladder cancer or prostate cancer
Age
From **55 years** old to **75 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **175**
Randomization (investigator's opinion)
Randomized
Randomization description
simple randomization method will be used. Five labels of treatment groups will be inserted in an excel file orderly and in the corresponding column, random numbers will be produced. By sorting the random numbers, the order of labels will randomly change. This randomized file will be used for the samples and cases who enrolled into our study and they will be grouped based on labels in the file.
Blinding (investigator's opinion)
Double blinded
Blinding description
ىThis is a multicenter, randomized , double blind, parallel group study.the Patients are randomised to 5 groups (discussed previously). Tamsulosin 0.4 mg is given to all participants .The finastride 5mg and 3mg , dutastride 0.5mg and 0.25mg and placebo tablets are identical in appearance and prepared by tansnim company . five treatment groups are labeled as A,B,C,D ,E by one of our collogues who is not care provider or assessor or data analyzer and each code represents one group and keep from the care provider and participants and assessor and data analyser until end of study. care provider and participants and data analyzer and outcome assessor are all blinded .Patients are assessed at visit 1 (screening visit) and If eligible, the patients will start in the double-blind study period where visits take place at weeks 4, 12, 24. a general physician who care for participants during trial is blinded in our study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of shahid beheshti university of medical sciences, urology and nephrology research
Street address
urology and nephrology research center,NO 103,ninth bustan(jafari),pasdaran avenue,tehran,iran
City
Tehran
Province
Tehran
Postal code
16666663111
Approval date
2020-11-01, 1399/08/11
Ethics committee reference number
IR.SBMU.UNRC.REC.1399.014

Health conditions studied

1

Description of health condition studied
medical treatment of benign prostate hyperplasia
ICD-10 code
D29.1
ICD-10 code description
Benign neoplasm of prostate

Primary outcomes

1

Description
the comparison of the maximum flow rate (qmax) before

, 3 and 6 moths after treatment in each group and among 5 groups under this study

Timepoint

before treatment and 3 ,6 months after treatment

Method of measurement

uroflowmetry

2

Description

the comparison of international prostate symptom score before, 3 and 6 months of treatment in each group and among 5 groups under treatment

Timepoint

before treatment ,3 and 6 months after tretment

Method of measurement

questionnaire

3

Description

the comparison of IIEF15 before ,3 and 6 months after treatment in each group among 5 groups under study

Timepoint

before treatment, 3 and 6 months after treatment

Method of measurement

IIEF15 Questionnaire

Secondary outcomes

1

Description

The comparison of complication after treatment among five groups under study

Timepoint

3 and 6 months after treatment

Method of measurement

questionnaire

Intervention groups

1

Description

Control group: patients with benign prostate hyperplasia take tamsulosin 0.4 mg (made by tasnim company)and placebo(made by tasnim company) daily for six months.

Category

Placebo

2

Description

Intervention group: patients with benign prostate hyperplasia take tamsulosin 0.4 mg and finastride 5 mg daily for six months (tamsulosin and finastride 5 mg made by tasnim company)

Category

Treatment - Drugs

3

Description

intervention group: patients with benign prostate hyperplasia take tamsulosin 0.4 mg and finastride 3 mg daily for six months (tamsulosin and finastride 5 mg made by tasnim company)

Category

Treatment - Drugs

4

Description

Intervention group: patients with benign prostate hyperplasia take tamsulosin 0.4 mg and dutastride 0.5 mg daily for six months (tamsulosin and dutastrude 0.5 made by tasnim company)

Category

Treatment - Drugs

5

Description

Intervention group: patients with benign prostate hyperplasia take tamsulosin 0.4 mg and dutastride 0.25 mg daily for six months(tamsulosin and dutastrude 0.25 mg made by tasnim company)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

shohada-e tajrish hospital

Full name of responsible person

amir reza abedi

Street address

Tajrish square

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2271 8014

Email

amirezabedi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

amir Reza Abedi

Street address

yaman street ,chamran highway

City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
amirezabedi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tandis company

Proportion provided by this source
40

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
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Amir Reza Abedi
Position
assistant professor of urology
Latest degree
Subspecialist
Other areas of specialty/work
Urology
Street address
Tajrish square, shohada-e tajrish hospital
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2271 8014
Email
amirezabedi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
amir Reza Abedi
Position
assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Urology
Street address
Tajrish suare, shohada-e tajrish hospital
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2271 8014
Email
amirezabedi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
amir reza abedi
Position
assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Urology
Street address
Tajrish square, shohada-e tajrish hospital
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2271 8014
Email
amirezabedi@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
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

IPD collected for the primary and secondary outcome

When the data will become available and for how long

when summary data are published

To whom data/document is available

for people working in academic institutions

Under which criteria data/document could be used

1- a new clinical trial is scheduled 2- affiliation of our center should be used

From where data/document is obtainable

amirezabedi@gmail.com

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

email

Comments