Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of therapeutic effect of prostatan (nettle) and pumpkin extract in a patient with benign prostatic hyperplasia

Protocol summary

Study aim
Comparison of therapeutic effect of prostatan (nettle) and prostaphitis (pumpkin extract) in patients with benign prostatic hyperplasia

Design
Clinical trial with control group, with factorial design, randomized, double-blind, phase 3 is performed on 100 patients

Settings and conduct
This study, which was a double-blind randomized controlled clinical trial on 100 patients referred to the Urology clinic of Vasei Hospital, Sabzevar, Iran who is over 50 years old, complained of urinary symptoms with benign prostatic hyperplasia. (DRE), paraclinical tests including PSA test and history entered will be performed. The sampling method will be available (easy) and individuals will be divided into two intervention groups 1 and 2 using random permutation blocks (4 blocks). The intervention group '1' of prostate capsules once a day and tamsulosin 0.4 mg once a day (standard treatment) and the intervention group 2 prostatite capsules (squash), once a day and tamsulosin 0.4 mg once a day (Standard treatment) will receive for eight weeks. In this study, in the times before the intervention (0), two weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 50 years old, with a proven benign prostate enlargement. Exclusion criteria: urological disease other than benign prostate enlargement; need for immediate surgical intervention for treatment.

Intervention groups
Intervention group 1 receives standard treatment and intervention group 2 in addition to standard pumpkin drops of Zarband company also consumes 10 drops daily.

Main outcome variables
PSA levels during; clinical signs of benign prostatic hyperplasia including symptoms of urinary retention and frequent urination

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210602051475N1**
Registration date: **2021-06-21, 1400/03/31**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-21, 1400/03/31**
Update count: **0**

Registration date
2021-06-21, 1400/03/31

Registrant information
Name
Reyhaneh Sedigh
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-06-02, 1400/03/12
Expected recruitment end date
2022-03-19, 1400/12/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Comparison of therapeutic effect of prostatan (nettle) and pumpkin extract in a patient with benign prostatic hyperplasia

Public title
Comparison of therapeutic effect of prostatan (nettle) and pumpkin extract in a patient with benign prostatic hyperplasia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 50 years old Benign prostate enlargement Administrative detention Frequent urination

Exclusion criteria:
Existence of urological disease other than benign prostate enlargement Need immediate surgical intervention for treatment Use of BPH-related drugs (stimulants and aggravators) in the last six months

Age
From **50 years** old

Gender
Male

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Random permutation block, which is one of the randomization methods in studies, is block randomization, in this method, usually the number of people assigned to each group is almost equal. In this method, blocks are formed based on the considered variables and within each block, half of the people are involved and half are considered as controls. Samples will be determined by random land block method with 4 blocks and using random numbers table of Random allocation software

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a double-blind clinical trial in such a way that for each person in the study, code '1' and '2' will be assigned that only the researcher will be aware of the type of groups and the participants and the treating physician groups are uninformed.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Sabzevar University of Medical Sciences

Street address
Sabzevar University of Medical Sciences, Shohada Hasteie Boulevard

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Sabzvar

Province
Razavi Khorasan

Postal code
9617913112

Approval date
2021-05-30, 1400/03/09

Ethics committee reference number
IR.MEDSAB.REC.1400.037

Health conditions studied

1

Description of health condition studied
Benign prostatic hyperplasia

ICD-10 code
N40

ICD-10 code description
Enlarged prostate

Primary outcomes

1

Description
Decreased PSA levels during treatment

Timepoint
In the times before the intervention (0), two weeks, four weeks and eight weeks after the intervention, the questionnaire will be filled in by the participants in the project.

Method of measurement
World Standard Scale for Symptoms of Prostate Hyperplasia and Uflometry

Secondary outcomes

empty

Intervention groups

1

Description
Control group: standard treatment includes tamsulosin 0.4 mg capsules daily for two months
Category
Treatment - Drugs

2

Description
Intervention group: tamsulosin capsules 0.4 mg daily and pumpkin drops 10 drops daily for two months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sabzevar Vasei Hospital
Full name of responsible person
Reyhaneh Sedigh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
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Position
student
Latest degree
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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
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
Yes - There is 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
Title and more details about the data/document
Only part of the data, such as the original outcome information, can be shared
When the data will become available and for how long
After printing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Researchers working in academic and scientific institutions
From where data/document is obtainable
reyhaneh sedigh 00989385167434 rsedigh@97gmail.com
What processes are involved for a request to access data/document
After printing the results
Comments