

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

Country

Iran (Islamic Republic of)

Phone

+98 51 3762 9386

Email address

rsedigh97@gmail.com

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

City

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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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Vaseie hospital, Shohada Hasteie Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Mohamad Hossein Saghi

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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

Reyhaneh Sedigh

Position

student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for updating data**Contact****Name of organization / entity**

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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