Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effect of Cucumis Melo L seeds oral product and Tamsulosin with Tamsulosin and placebo in reducing the symptoms of patients with benign prostatic hypertrophy.

Protocol summary

Study aim
General goal Use of Cucumis melo L seeds in the treatment of lower urinary tract symptoms (LUTS) due to Benign Prostatic Hyperplasia (BPH)

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 80 patients.

Settings and conduct
This study is a prospective human clinical trial ,that will be done ,on 80 men with benign prostatic hyperplasia (BPH) in the age group of 45 to 75 years, who referred to Hasheminejad Hospital clinic and had symptoms of lower urinary tract symptoms (LUTS).

Participants/Inclusion and exclusion criteria
Inclusion criteria All patients aged 45 to 75 years with BPH, including at least one of the following, have an International Score of Prostate Symptoms (IPSS) greater than 13 at screening, a PSA greater than 3 ng / ml, and a prostate volume greater than 30 mm. Cube diagnosed by ultrasound, and patients who are able and willing to sign written consent. Exclusion criteria Surgery, infection, lower urinary tract disease (bladder stones, neurogenic bladder, bladder malignancy, urethral stricture, hematuria), Diabetes, Heart disease (heart failure, MI, unstable angina), uncontrolled hepato-renal disease, use of effective drugs Bladder and prostate (anticholinergics, sympathomimetics, antidepressants) Patients who are unable to use oral medication. Perform any drug intervention simultaneously. Allergy to medicinal plants.

Intervention groups
Intervention group: Will received Tamsulosin (0.4 mg per night, 1 piece) with Cucumis melo L seeds 500 mg oral capsule three times daily after each meal for up to 6 weeks. The medicine is made by a pharmacist. The control group received Tamsulosin (0.4 mg 1 per night) with placebo oral capsules (500 mg of starch) three times daily after each meal for up to 6 weeks.

Main outcome variables
Patients' urinary symptoms

General information

Reason for update

Acronym
BPH

IRCT registration information
IRCT registration number: **IRCT20180712040446N3**
Registration date: **2022-03-07, 1400/12/16**
Registration timing: **prospective**

Last update: **2022-03-07, 1400/12/16**
Update count: **0**

Registration date
2022-03-07, 1400/12/16

Registrant information

Name
Atefe Sharif

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2247 3630

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-21, 1401/01/01

Expected recruitment end date
2022-11-21, 1401/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of Cucumis Melo L seeds oral product and Tamsulosin with Tamsulosin and placebo in reducing the symptoms of patients with benign prostatic hypertrophy.

Public title
Effect of Cucumis Melo L seeds on patients with benign prostatic hypertrophy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients aged 45 to 75 years with BPH who include at least one of the following: International Score of Prostate Symptoms (IPSS) over 13 at the time of screening PSA higher than 3 ng / ml. Prostate volume greater than 30 mm detected by ultrasound Patients who are able and willing to sign a written consent.
Exclusion criteria:
Surgery, infection, lower urinary tract disease (bladder stones, neurogenic bladder, bladder malignancy, urethral stricture, hematuria Gross) Diabetes, Heart disease (heart failure, MI, unstable angina), Hepato-renal disease Use of drugs affecting the bladder and prostate (anticholinergics, sympathomimetics, antidepressants) Patients who are unable to use oral medication. Participate in concurrent drug intervention. Allergy to medicinal plants.
Age
From **45 years** old to **75 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the balanced block randomization method. Random division is done in the form of "blocks" of predetermined size. For example, if the size of block is 6, the operation of random division until the third one person is randomly assigned to one group, and then individuals are automatically assigned to another group until a 6-piece block is completed. The features of this method are that it is easy to implement and balance in the number of groups is guaranteed.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, in addition to the patient, health care personnel, data collectors, and those evaluating the outcome are blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Iran University of Medical Sciences
Street address
Shahid Hemmat Highway next to Milad Tower, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2022-02-04, 1400/11/15
Ethics committee reference number
IR.IUMS.REC.1400.1061

Health conditions studied

1

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

2

Description of health condition studied
Lower Urinary Tract Symptoms
ICD-10 code
N40.1
ICD-10 code description
Enlarged prostate with lower urinary tract symptoms

Primary outcomes

1

Description
تغییرات امتیاز بین اللملی علائم پروستات
Timepoint
Before the intervention and 2 weeks after the

intervention

Method of measurement

Questionnaire

2

Description

Q max

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

Euroflowmetry

3

Description

Prostate volume

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

Sonography

Secondary outcomes

1

Description

Prostate specific antigen (PSA)

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

ELISA test

2

Description

Drug side effects

Timepoint

During the study and two weeks after the study

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Will received Tamsulosin (0.4 mg per night, 1 piece) with Cucumis melo L seeds 500 mg oral capsule three times daily after each meal for up to 6 weeks. The medicine is made by a pharmacist.

Category

Treatment - Drugs

2

Description

Control group: The control group received Tamsulosin (0.4 mg 1 per night) with placebo oral capsules (500 mg of starch) three times daily after each meal for up to 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hasheminejad Kidney Center

Full name of responsible person

Dr. Pejman Shadpour

Street address

Vali-nejad Str., Vanak Sq. Vali-e-asr Boul, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Hossein Kiwani

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Health Management Research Institute

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

Iran University of Medical Sciences

Full name of responsible person

Dr. Pejman Shadpour

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Pejman Shadpour

Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Atefe Sharif

Position

Non-faculty specialist physician

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

محرمانه بودن

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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