Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The exploring the Effect of nettle extract on decreasing urinary problems and prostate size in elderly with benign prostatic hyperplasia

Protocol summary

Study aim

The exploring the Effect of nettle extract on decreasing urinary problems and prostate size in elderly with benign prostatic hyperplasia

Design

A randomized controlled clinical trial with parallel groups, three blinded, randomized

Settings and conduct

Patients referred to the urology clinic with definitive diagnosis of benign prostatic hyperplasia are divided into two groups of experimental and control. Samples were divided into control (n = 40) and experimental (n = 40) groups. Urinary Tract Questionnaire will be used to measure urinary problems. Both groups will then receive routine medical and nursing treatments, but the patients in the experimental group will receive 300 mg twice daily oral capsule in addition to routine nursing interventions after 8 weeks. Weekly urinary problems (check list) and prostate volume (via ultrasound) will be assessed in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria • Elderly over 60 years with BPH diagnosis • No urinary tract infection or bladder stones • Patients in the BPH drug phase Exclusion criteria • Willingness not to continue cooperation • Any drug-induced allergic side effects

Intervention groups

Both groups will receive regular medical and nursing treatments, but patients in the test group will receive 300 mg of nettle root extract twice a day, in the form of oral capsules, for 8 weeks in addition to receiving routine nursing interventions.

Main outcome variables

The variable is the main consequence of the size of the prostate gland. Before and after consuming the extract of nettle root, it would examined by test and ultrasound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100124003146N9**
Registration date: **2020-04-12, 1399/01/24**
Registration timing: **prospective**

Last update: **2020-04-12, 1399/01/24**
Update count: **0**

Registration date

2020-04-12, 1399/01/24

Registrant information

Name
Ismail Azizi-Fini
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 31 5554 0021
Email address
azizi-es@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-07-20, 1399/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The exploring the Effect of nettle extract on decreasing urinary problems and prostate size in elderly with benign prostatic hyperplasia

Public title
The exploring the Effect of nettle extract on decreasing urinary problems and prostate size in elderly with benign prostatic hyperplasia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The elderly with benign prostatic hypertrophy No urinary tract infection or bladder stones No history of allergy to dark mint plants such as nettle
Exclusion criteria:
refuse to continue cooperation The occurrence of any drug-induced allergic side effects
Age
From **60 years** old
Gender
Male

Phase
N/A
Groups that have been masked

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

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients who met the inclusion criteria will be randomly divided into intervention and control groups by block randomization (Blocks with size 4).
Blinding (investigator's opinion)
Triple blinded
Blinding description
Only researchers will know the contents of packages. The prescriber, who is a co-physician with the plan, will not know if the package contains the nettle capsule or placebo (starch). Packages will be marked with code. Patients will also be unaware of the contents of the packages in order not to switch medications. Patients will be told not to consume nettle plant products during the course of the plan. Also, the statistical analyst will not know the test and control groups in order to avoid bias in the analysis of results. So this study will be three-blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
5th kilometer Qotb Ravandi blouvar
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Province
Isfehan
Postal code
8715981151
Approval date
2020-03-14, 1398/12/24
Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1398.072

Health conditions studied

1

Description of health condition studied
Benign Prostatic Hyperplasia
ICD-10 code
D29.1
ICD-10 code description
Benign neoplasm of prostate

Primary outcomes

1

Description
Prostate size
Timepoint
8 weeks
Method of measurement
Specific antigen prostate test and prostate sonography and questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The experimental group will receive 300 mg of nettle root extract twice daily for 8 weeks in addition to the usual nursing interventions. After 8 weeks, urinary problems (by checklist) and prostate volume (by ultrasound) will be checked again.
Category
Treatment - Drugs

2

Description
Control group: Control group will receive placebo twice daily for 8 weeks in addition to usual placebo nursing interventions. After 8 weeks, urinary problems (by checklist) and prostate volume (by ultrasound) will be checked again.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti hospital of Kashan
Full name of responsible person
Dr. Hossein Mahmoudi
Street address
Kashan University of Medical Sciences, Faculty of Nursing and Midwifery
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Dr Esmail Azizi-Fini
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assisstant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Yes - There is 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

the results related to the main outcome will be distributed.

When the data will become available and for how long

after the publication of the article

To whom data/document is available

all people

Under which criteria data/document could be used

data will be confidential

From where data/document is obtainable

aziz-es@kaums.ac.ir

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

the process will be announced later.

Comments