Clinical Trial Protocol
Iranian Registry of Clinical Trials
17 May 2022

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.
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
City
kashan
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
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
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
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Phone
Person responsible for updating data

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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