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
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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
- **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
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Kashan University of Medical Sciences, Faculty of Nursing and Midwifery
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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
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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Person responsible for updating data

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Sharing plan
Deidentified Individual Participant Data Set (IPD)

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