

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 be 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)

##### Phone

+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

**City**

kashan

**Province**

Isfahan

**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

##### City

kashan

##### Province

Isfahan

##### Postal code

8715981151

##### Phone

+98 31 5554 0026

##### Email

msaeidm63@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Hamid Reza Banafshe

##### Street address

5th kilometer Qotb Ravandi Blouvar.Parastar blouvar

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##### Province

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##### Phone

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##### Email

msaeidm63@gmail.com

##### 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

assisstant professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

##### Street address

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##### Province

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## Person responsible for scientific inquiries

#### Contact

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Kashan University of Medical Sciences

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr Esmail Aziz-Fini

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**City**

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**Province**

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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**