Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Evaluation of the effect of Nigella sativa extraction supplement for benign prostatic hyperplasia patients treatment: A randomized placebo-controlled clinical trial

Protocol summary

Study aim
Nigella sativa extraction supplement will be utilized for Benign prostatic hyperplasia patients treatment.

Design
Clinical trial with intervention and control groups, single-blinded, randomized, phase 3 on 50 patients. Random numbers technique will be used for randomization.

Settings and conduct
In this clinical trial study, 60 individuals with benign prostate hyperplasia that refer to Imam Reza Hospital of Tabriz, will be randomly divided into two groups of 30 individuals that the target and control groups will receive Nigella sativa extraction supplement and placebo, respectively. Type of blinding will be single-blinded and all names and personal information of the patients will be encoded at the beginning of study and it will completely remain confidential.

Participants/Inclusion and exclusion criteria
Including criteria: Having benign prostate hyperplasia with or without lower urinary tract symptoms, eligible to participate in the study Excluding criteria: Presence of possible allergy to Nigella sativa extraction supplement

Intervention groups
Intervention group is including of benign prostate hyperplasia that receive Nigella sativa extraction supplement intervention. Comparison group is including of benign prostate hyperplasia that receive placebo intervention.

Main outcome variables
Evaluation of urinary problems, measuring the prostatic volume, measuring the remained urine volume, evaluating prostatic specific antigen (PSA) level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201108049311N4**
Registration date: **2021-09-06, 1400/06/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-06, 1400/06/15**
Update count: **0**

Registration date
2021-09-06, 1400/06/15

Registrant information

Name
Seyyedeh Mina Hejazian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3336 9331

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smhjz.biotech@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-23, 1400/06/01

Expected recruitment end date
2022-08-23, 1401/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Nigella sativa extraction supplement for benign prostatic hyperplasia patients

treatment: A randomized placebo-controlled clinical trial

Public title
Effect of Nigella sativa extraction supplement in benign prostatic hyperplasia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having benign prostate hyperplasia with or without lower urinary tract symptoms Eligible to participate in the study
Exclusion criteria:
Presence of possible allergy to Nigella sativa extraction supplement
Age
No age limit
Gender
Male

Phase
2
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
This study will be perform by simple randomization. patients will be numbered based the referred date and on the other hand, 60 numbers will be written from 1 to 60 and then 30 numbers will be randomly selected among them that will be Nigella sativa extraction supplement receiving. Other patients number will receive placebo.
Blinding (investigator's opinion)
Single blinded
Blinding description
The present study will be perform as single-blinded and only patients will be blinded. Nigella sativa extraction supplement and placebo will be placed in similar and coded cans and volunteers will not be informed about receiving the brand drug or the other drugs. Furthermore, the placebo will be similar with the drug in terms of appearance (shape and color), the taste and smell. Therefore, patients will be unaware from prescribed drugs and assignment of utilized drug in this study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Golgasht street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-07-26, 1400/05/04
Ethics committee reference number
IR.TBZMED.REC.1400.377

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
Evaluation of urinary problems
Timepoint
At first, 2, 4 and 8 weeks after the drug intervention
Method of measurement
Designed IPSS questionnaire

2

Description
Measuring the prostatic volume
Timepoint
At first, 2, 4 and 8 weeks after the drug intervention
Method of measurement
Evaluation of ultrasound results

Secondary outcomes

1

Description
Measuring the remained urine volume
Timepoint
At first, 2, 4 and 8 weeks after the drug intervention
Method of measurement
Evaluation of ultrasound results

2

Description
Evaluating prostatic specific antigen (PSA) level
Timepoint
At first, 2, 4 and 8 weeks after the drug intervention
Method of measurement
ELISA test from blood samples

Intervention groups

1

Description
Intervention group: capsule recipients containing 75 milligram hydroalcoholic Nigella sativa extraction of Zahravi pharmatheutical company in the form of two capsules per meal (three times a day) which will be taken orally.
Category
Treatment - Drugs

2

Description
Control group: placebo capsule recipients containing excipient in the form of two capsules per meal (three times a day) which will be taken orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital of Tabriz
Full name of responsible person
Dr. Mohammadreza Ardalan
Street address
Imam Reza hospital, Golgasht St, Tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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Samiei.moh@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammadreza Ardalan
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific

inquiries

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Position
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Person responsible for updating data

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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
There is no more information.

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