

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)

Phone

+98 41 3336 9331

Email address

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 pharmaceutical 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

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3337 3992

Email

Ardalan34@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiei

Street address

Tabriz university of medical sciences, Golgasht St, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3335 7310

Email

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

Nephrology

Street address

Kidney research center, Tabriz university of Medical Sciences, Golgasht St., Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

51566614756

Phone

+98 41 3337 3992

Email

ardalan34@yahoo.com

Person responsible for scientific

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

Internal Medicine

Street address

Kidney research center, Tabriz university of Medical Sciences, Golgasht St., Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

51566614756

Phone

+98 41 3337 3992

Email

ardalan34@yahoo.com

Person responsible for updating data

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

Internal Medicine

Street address

Kidney research center, Tabriz university of Medical Sciences, Golgasht St., Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

51566614756

Phone

+98 41 3337 3992

Email

ardalan34@yahoo.com

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