Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The effectiveness of Nigella sativa seed oil compared with placebo on blood pressure in hypertensive patients

Protocol summary

Summary

The present study aims to evaluate the efficacy of treatment with an oral Nigella sativa (NS) seed oil in hypertensive patients. Subjects will be informed that they may take NS oil or placebo in the informed consent. Therefore, patients aren't aware of their therapeutic group they will be assigned. In addition, neither patients nor medical staff will be aware of the type of oils in the container (Ns oil or placebo). Only the researcher is aware of the code written on the container of the oils; so, this study is a double-blind, parallel clinical trial. Hypertensive patients with SBP /DBP ≥ 140/90 mmHg were eligible for inclusion. Patients who smoke and patients who consume antioxidant products aren't enrolled in the study. One hundred of patients attending the Quaem outpatient’s clinic who meet our inclusion criteria will take part in this study. By using random numbers (created by computer) subjects will randomly allocate to one of two experimental groups: a placebo and a test group. Thus, 50 cases in each treatment arm receive placebo or NS oil. In the intervention group, 5 ml oral NS oil is administered daily for 8 weeks. Patients in the control group receive placebo in the same way. Systolic and diastolic pressure (during intervention) and serum Malondialdehyde [MDA] (before and 8 weeks after intervention) will be checked as primary outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013082614477N1**
Registration date: **2013-10-03, 1392/07/11**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-10-03, 1392/07/11

Registrant information

Name
Zhila Taherzadeh
Name of organization / entity
Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 1882 3255
Email address
taherzadehzh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad university of medical sciences

Expected recruitment start date

2013-11-21, 1392/08/30

Expected recruitment end date

2017-01-01, 1395/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Nigella sativa seed oil compared with placebo on blood pressure in hypertensive patients

Public title

Effect of Nigella sativa seed oil in treatment of hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Hypertensive patients with SBP/DBP ≥ 140/90 mmHg who do not suffer from heart, kidney and

liver failure were eligible for inclusion. Exclusion criteria: Patients who smoke and patients who consume antioxidant products aren't enrolled in the study.

Age
From **45 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Regional Committee for Research Ethics, Mashhad University of Medical Sciences

Street address
Ghoreishi building, Daneshgah Street

City
Mashhad

Postal code
91375-345

Approval date
2013-06-08, 1392/03/18

Ethics committee reference number
92/191552

Health conditions studied

1

Description of health condition studied
Hypertensive patients

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Diastolic Blood pressure

Timepoint
During the intervention (every week)

Method of measurement
blood pressure manometer

2

Description
Systolic Blood pressure

Timepoint
During the intervention (every week)

Method of measurement
blood pressure manometer

3

Description
Malondialdehyde [MDA] in serum

Timepoint
Before and 8 weeks after intervention

Method of measurement
Spectrophotometry

Secondary outcomes

1

Description
Blood sugar

Timepoint
Before and 8 weeks after the intervention

Method of measurement
Biochemical test

2

Description
Lipid profile

Timepoint
Before and 8 weeks after the intervention

Method of measurement
Biochemical test

Intervention groups

1

Description
The patients in Intervention group will orally receive 5 ml /day of Nigella Sativa seed oil for 8 weeks in addition to their current treatment regimen.

Category
Treatment - Drugs

2

Description
Control group will orally receive 5 ml /day of Sunflower seed oil for 8 weeks in addition to their current treatment regimen. Sunflower seed oil, which is used as a placebo, has no real effect on blood pressure. This oil has very similar physical characteristics to NS oil. Only the code written on the containers are different from each other. Frequency and duration of using placebo oil in the control group are absolutely the same as NS oil in the intervention group.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Quaem Hospital

Full name of responsible person
Zhila Taherzadeh

Street address
School of pharmacy, Pardis university campus, Park square

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mashhad university of medical sciences

Full name of responsible person
Dr. Mohsen Tafaghodi (Research Deputy of Mashhad University of Medical Sciences)

Street address
School of pharmacy, Pardis university campus, Park square

City
Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research, Mashhad university of medical sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Zamanzadeh Mansoureh

Position
Pharmacy student

Other areas of specialty/work

Street address
School of pharmacy, Pardis university campus, Park square

City
Mashhad

Postal code
91775-1365

Phone
+98 51 1882 3255

Fax
+98 51 1882 3251

Email
Zamanzadehm861@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Zhila Taherzadeh

Position
Ph.D

Other areas of specialty/work

Street address
School of pharmacy, Pardis university campus, Park square

City
Mashhad

Postal code
91775-1365

Phone
+98 51 1882 3255

Fax
+98 51 1882 3251

Email
Taherzadehzh@mums.ac.ir; Eslamia@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Zamanzadeh Mansoureh

Position
Pharmacy student
Other areas of specialty/work
Street address
School of pharmacy, Pardis university campus, Park square
City
Mashhad
Postal code
91775-1365
Phone
+98 51 1882 3255
Fax
+98 51 1882 3251
Email
Zamanzadehm861@mums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty