

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

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

Protocol summary

2013-10-03, 1392/07/11

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 \geq 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

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 \geq 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

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Zamanzadeh Mansoureh

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Pharmacy student

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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