Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Hypolipidemic effects of Nigella Sativa L. Seeds oil in healthy volunteers: a randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Summary

Background: Several formulations of the Nigella sativa L. seeds (black seed) have been used in traditional medicine for treatment and prevention of a wide range of diseases including hyperlipidemia. But blood lipid lowering effects of its oil in clinical study is of an interest. Objective: The present study was undertaken to explore the possible blood lipid lowering effects of the black seed oil on healthy volunteers. Methods: A randomized clinical trial was conducted in 70 healthy volunteers referring to Bagiatallah hospital. The subjects were randomly selected and enrolled in to two groups of 35 each. One group received 2.5 ml black seed oil and the other group received similarly 2.5 ml mineral oil two times a day. The fasting blood Triglyceride, Cholesterol, HDL, LDL, Glucose, ALT, AST, BUN, Cr, and HbA1C were determined at the baseline and after 8 weeks. Results: Results showed that significant decrease in fasting blood cholesterol, LDL, Triglyceride, glucose and HbA1c levels in black seed oil treated volunteers as compared to placebo group at the end of the study. No notable liver, kidney and gastrointestinal side effects were observed in these two groups side effects were observed in these two groups. Conclusion: Administration of 5 ml black seed oil daily to healthy volunteers for 8 weeks had beneficial effects on improving lipid profile without any adverse effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112271157N5**
Registration date: **2012-01-05, 1390/10/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-01-05, 1390/10/15

Registrant information

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Hasan Fallah Huseini
Name of organization / entity
Institute of Medicinal Plants
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Recruitment status

Recruitment complete

Funding source
Institute of Medicinal Plants, ACECR and Baqiyatallah University of Medical Sciences

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2011-05-22, 1390/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Hypolipidemic effects of Nigella Sativa L. Seeds oil in healthy volunteers: a randomized, double-blind, placebo-controlled clinical trial

Public title

Hypolipidemic effects of Nigella Sativa L. seeds oil in healthy volunteers

Purpose

Health service research

Inclusion/Exclusion criteria
Inclusion criteria: healthy Iranian volunteers aged between 40 to 60 years; with fasting blood cholesterol 200 to 300 mg/dl; fasting blood glucose 80 to120 mg/dl and weight 55 to 85 kg
Age
From **25 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **70**
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
Baqiyatallah University of Medical Sciences
Street address
Baqiyatallah University of Medical Sciences, Tehran, Iran
City
Tehran
Postal code
1484958693
Approval date
2010-12-12, 1389/09/21
Ethics committee reference number
22-340/s

Health conditions studied

1

Description of health condition studied
Healthy Volunteers
ICD-10 code
Z01
ICD-10 code description
Other special examinations and investigations of persons without complaint or reported diagnosis

Primary outcomes

1

Description
Cholesterole
Timepoint
At starting of the study and after 8 weeks
Method of measurement
The fasting blood cholesterl level determined in laboratory

Secondary outcomes

1

Description
SGPT
Timepoint
At starting of the study and after 8 weeks
Method of measurement
The fasting blood SGPT level determined in laboratory

2

Description
LDL
Timepoint
At starting of the study and after 8 weeks
Method of measurement
The fasting blood LDL level determined in laboratory

3

Description
Hba1c
Timepoint
At starting of the study and after 8 weeks
Method of measurement
The fasting blood Hba1c level determined in laboratory

4

Description
Glucose
Timepoint
At starting of the study and after 8 weeks
Method of measurement
The fasting blood Glucose level determined in laboratory

5

Description
Creatinine
Timepoint
At starting of the study and after 8 weeks
Method of measurement
The fasting blood Creatinine level determined in laboratory

6

Description

SGOT

Timepoint

At starting of the study and after 8 weeks

Method of measurement

The fasting blood SGOT level determined in laboratory

7

Description

BUN

Timepoint

At starting of the study and after 8 weeks

Method of measurement

The fasting blood BUN level determined in laboratory

8

Description

Triglyceride

Timepoint

At starting of the study and after 8 weeks

Method of measurement

determined in fasting blood sample in laboratory

9

Description

Hdl

Timepoint

At starting of the study and after 8 weeks

Method of measurement

determined in fasting blood sample in laboratory

Intervention groups

1

Description

2.5 ml black seed oil two times a day after meal for 8 weeks

Category

Treatment - Drugs

2

Description

2.5 ml mineral oil two times a day after meal for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroentrology and Liver diseases Research Center, Baqiyatallah University of Medical Sciences

Full name of responsible person

Mohtashami Reza

Street address

Vanak Squer, Molasadra Ave

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Institute of Medicinal Plants, ACECR

Full name of responsible person

Hassan ali Nqdi badi

Street address

Tehran-Qazwain Highway Research City Kavosh, Jahad daneshgahi research society Kraj

City

Kraj

Grant name

روغن سیاه دانه: 84/ 1389/9/10 /س

Grant code / Reference number

1142-33

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

Yes

Title of funding source

Institute of Medicinal Plants, ACECR

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Reza Mohtashami

Street address

Baqiyatallah University of Medical Sciences,Tebo-o-Din Center, Vanak squer, Molasadra Ave,Tehran, Iran

City

Tehran

Grant name

456/l/1389

Grant code / Reference number

111-306

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

Yes

Title of funding source

Baqiyatallah University of Medical Sciences

Proportion provided by this source

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
Institute of Medicinal Plants

Full name of responsible person
Hassan Fallah Huseini

Position
Ph.d

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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