

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Name

Hasan Fallah Huseini

###### Name of organization / entity

Institute of Medicinal Plants

###### Country

Iran (Islamic Republic of)

###### Phone

+98 26 3476 4010

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fallah@imp.ac.ir

##### 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 to 120 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

Cholesterol

#### Timepoint

At starting of the study and after 8 weeks

#### Method of measurement

The fasting blood cholesterol 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**  
Gastroentology 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  
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**Grant name**  
456/1/1389  
**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

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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*