

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of Nigella sativa consumption on lipid profile, liver enzymes, inflammatory factors and hepatic steatosis in patients with Non-Alcoholic Fatty Liver Disease (NAFLD)

Protocol summary

Study aim

The effect of Nigella sativa supplementation on serum lipids, liver enzymes, inflammatory markers and hepatic steatosis in patients with nonalcoholic fatty liver.

Design

Randomized, double-blind, placebo-controlled

Settings and conduct

In this study, patients with non-alcoholic fatty liver referring to Baqiatalah Hospital, with tendency to participate in the study with informed consent are recruited. After 12 to 14 hours of fasting, 5 cc of blood is taken to measure lipids profile, inflammatory factors and other serum biochemical parameters and kept in the freezer. Participants are randomly divided and classified into two groups: supplement and placebo group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 years and above; level of liver enzymes (ALT and AST) 1.5 times greater than normal; Evidence of nonalcoholic steatohepatitis in Fibroscan.
Exclusion criteria: Not continue to cooperate; consumed less than 90% of supplements at the end of the sixth and twelfth week of study.

Intervention groups

Patients group supplement will be received daily 2 grams of Nigella sativa for three months and Patients in the control group will be received placebo daily 2 grams.

Main outcome variables

Low Density Lipoprotein Cholesterol (LDL-C), High Density Lipoprotein Cholesterol (HDL-C), Triglyceride (TG), Total Cholesterol, Fasting Blood Sugar (FBS), Insulin,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100524004010N25**

Registration date: **2018-07-24, 1397/05/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-09, 1397/11/20**

Update count: **1**

Registration date

2018-07-24, 1397/05/02

Registrant information

Name

Azita Hekmatdoost

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
National Institute of Nutrition Research

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-02-28, 1395/12/10

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Nigella sativa consumption on lipid profile, liver enzymes, inflammatory factors and hepatic

steatosis in patients with Non-Alcoholic Fatty Liver Disease (NAFLD)

Public title

The effect of Nigella sativa on Non-Alcoholic Fatty Liver Disease (NAFLD)

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

18 years old and older Evidence of nonalcoholic steatohepatitis in Fibroscan (Controlled Attenuation Parameter (CAP) score > 263) absence of pregnancy and lactation

Exclusion criteria:

Unwillingness to continue study for any reason.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to receive Nigella sativa or placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

For randomization process, simple randomization method is used by random number table. At the beginning of the study, in order to blind the researchers to group assignment, the cans containing the capsules are coded by another person instead of the researcher to A and B as intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Nutrition and Food Technology Research Institute, Shahid Beheshti University of Medical Sci

Street address

West Arghavan, Sanaat Square, Farahzadi Boulevard,

Shahrake Gharb

City

Tehran

Province

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Postal code

123456

Approval date

2017-02-19, 1395/12/01

Ethics committee reference number

IR.SBMU.nnftri.Rec.1395.121

Health conditions studied

1

Description of health condition studied

Non alcoholic fatty liver disease

ICD-10 code

(K75.8)

ICD-10 code description

Other specified inflammatory liver diseases

Primary outcomes

1

Description

HOMA

Timepoint

Beginning and end of the study

Method of measurement

Calculation

2

Description

TNF- α

Timepoint

Beginning and end of the study

Method of measurement

Elisa

3

Description

IL-6

Timepoint

Beginning and end of the study

Method of measurement

Elisa

4

Description

Hepatic Steatosis

Timepoint

Beginning and end of the study

Method of measurement

Ultrasound

5

Description

LDL-C

Timepoint

Beginning and end of the study

Method of measurement

Enzymatic methods using a kit

6

Description

HDL-C

Timepoint

Beginning and end of the study

Method of measurement

Enzymatic methods using a kit

7

Description

TG

Timepoint

Beginning and end of the study

Method of measurement

Enzymatic methods using a kit

8

Description

total Cholesterol

Timepoint

Beginning and end of the study

Method of measurement

Enzymatic methods using a kit

9

Description

Serum Insulin

Timepoint

Beginning and end of the study

Method of measurement

Radioimmunoassay

10

Description

FBS

Timepoint

Beginning and end of the study

Method of measurement

Enzymatic methods using a kits

11

Description

AST

Timepoint

Beginning and end of the study

Method of measurement

Enzymatic methods using a kits

12

Description

ALT

Timepoint

Beginning and end of the study

Method of measurement

Enzymatic methods using a kit

13

Description

Total energy intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

14

Description

Carbohydrate intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

15

Description

Protein intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

16

Description

total fat intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

17

Description

SFA intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

18

Description

PUFA intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

19

Description

MUFA intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

20

Description

fiber intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

Secondary outcomes

1

Description

Total energy intake

Timepoint

Beginning and end of the study

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: 2 gr per day nigella sativa daily for 3 months

Category

Treatment - Other

2

Description

Placebo group: 2 gr per day starch daily for 3 months

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

The liver and gastroenterology clinic Baqiyat Allah Hospital

Full name of responsible person

Mina Darand

Street address

Mollasadra Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences, National Nutrition and Food Technology Research

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences, National Nutrition and Food Technology Research

Proportion provided by this source

100

Public or private sector

Private

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

Shahid Beheshti University of Medical Sciences, National Nutrition and Food Technology Research

Full name of responsible person

Azita Hekmatdoost

Position

Nutritionist

Latest degree

Specialist

Other areas of specialty/work

Nutrition

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Mina Darand

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable