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 reffering 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 recived daily 2 grams of Nigella sativa for three months and Patients in the control group will be recived placebo daily2 grams.

Main outcome variables
Low Density Lipoprotein Cholestrol (LDL-C), High Density Lipoprotein Cholestrol (HDL-C), Triglyceride(TG), Total Cholestrol, 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 Boulvard, Shahrake Gharb
City
Tehran
Province
Tehran
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
Begining and end of the study
Method of measurement
Calculation

2

Description
TNF-α
Timepoint
Begining and end of the study
Method of measurement
Elisa

3

Description
IL-6
Timepoint
Begining and end of the study
Method of measurement
Elisa

4

Description
Hepatic Steatosis
Timepoint
Begining and end of the study
Method of measurement
Ultrasound

5

Description
LDL-C
Timepoint
Begining and end of the study
Method of measurement
Enzymatic methods using a kit

6

Description
HDL-C
Timepoint
Begining and end of the study
Method of measurement
Enzymatic methods using a kit

7

Description
TG
Timepoint
Begining and end of the study
Method of measurement
Enzymatic methods using a kit

8

Description
total Cholesterol
Timepoint
Begining and end of the study
Method of measurement
Enzymatic methods using a kit

9

Description
Serum Insulin
Timepoint
Begining and end of the study
Method of measurement
Radioimmunoassay

10

Description
FBS
Timepoint
Begining and end of the study
Method of measurement
Enzymatic methods using a kits

11

Description
AST
Timepoint
Begining and end of the study
Method of measurement
Enzymatic methods using a kits

12

Description
ALT
Timepoint
Begining and end of the study
Method of measurement
Enzymatic methods using a kit

13

Description
Total energy intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

14

Description
Carbohydrate intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

15

Description
Protein intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

16

Description
total fat intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

17

Description
SFA intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

18

Description
PUFA intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

19

Description
MUFA intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

20

Description
fiber intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

Secondary outcomes

1

Description
Total energy intake
Timepoint
Begining 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
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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
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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