Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The clinical trial of evaluation of the effect of black cumin (nigella sativa) extract supplementation on serum levels of some inflammatory markers, liver enzymes, lipid profile ,insulin and fasting plasma glucose in patients with non-alcoholic fatty liver disease

Protocol summary

Summary

The aim of the study is to alleviate the symptoms of fatty liver disease. This study is a randomized (through Sealed envelope method), double-blind clinical trial consisted of 44 men and women suffering from non-alcoholic fatty liver disease (22 patients in each treatment and placebo group). Patients with pregnancy and lactation, liver transplantation, rapid weight loss, diabetes and thyroid problems and patients who use medications such as corticosteroids or receive total parenteral nutrition are excluded. The intervention group will receive Black Seed Oil, one capsule (1000 mg) a day after lunch for 2 months. The control group will receive Paraffin oil, one capsule (1000mg) each day after lunch for 2 months. Patients will be followed up every 2 weeks. At the beginning and at the end of the study, blood sample will be taken from the patients after 12-14 hours fasting period. the primary outcomes of the study are inflammatory markers including IL-6, TNF-α, HS-CRP; fasting blood glucose (FBS), insulin level, liver enzymes (ALT, AST, GGT); total cholesterol (TC); high-density lipoprotein (HDL-C) and triglycerides (TG) and low density lipoproteins (LDL-C) will be calculated. The secondary outcomes of the study are Anthropometric measurements, systolic blood pressure (SBP), diastolic (DBP), diet and physical activity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012232109N1**
Registration date: **2017-03-12, 1395/12/22**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2017-03-12, 1395/12/22

Registrant information

Name

Mohammad Rashidmayvan

Name of organization / entity

Ahvaz Jundishapour University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapour University of Medical Sciences

Expected recruitment start date

2017-04-24, 1396/02/04

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The clinical trial of evaluation of the effect of black cumin (nigella sativa) extract supplementation on serum levels of some inflammatory markers, liver enzymes, lipid profile ,insulin and fasting plasma glucose in patients

with non-alcoholic fatty liver disease

Public title
The effect of black cumin on non alcholic fatty liver
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients aged 20 to 60 years diagnosed with nonalcoholic fatty liver by ultrasound, confirmed by a radiologist and a gastroenterologist. Exclusion criteria: pregnancy and lactation; liver transplantation; smoking; alcohol and drug abuse; consuming drugs such as corticosteroids, amiodarone, tamoxifen, methotrexate; receiving total parenteral nutrition; rapid weight loss; diabetes; heart failure; thyroid problems; kidney disease; hereditary hemochromatosis and Wilson disease; have a positive test for hepatitis C, B and autoimmune hepatitis; alpha-1 antitrypsin deficiency.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Sealed envelope method

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences
Street address
Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences, Ahvaz Jundishapur University of Medical Sciences, Golestan Ave.
City
Ahvaz
Postal code
15794-61357
Approval date
2017-01-21, 1395/11/02
Ethics committee reference number
IR.AJUMS.REC.1395.695

Health conditions studied

1

Description of health condition studied
Non alcholic fatty liver
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Tumor necrosis factor
Timepoint
before and 8 weeks after intervention
Method of measurement
ELISA

2

Description
Interleukin 6
Timepoint
before and 8 weeks after intervention
Method of measurement
ELISA

3

Description
liver enzymes(aspartate aminotransfrase,alanin aminotransferase,gama glutamil transferase)
Timepoint
before and 8 weeks after intervention
Method of measurement
Labratory kits

4

Description
C reactive protein
Timepoint
before and 8 weeks after intervention
Method of measurement
ELISA

5

Description
lipid profiles(triglycrid,HDL,LDL and total chollestrol)
Timepoint
before and 8 weeks after intervention
Method of measurement
Labratory kits

6

Description
insulin
Timepoint
before and 8 weeks after intervention
Method of measurement
ELISA

7

Description
fast blood sugar
Timepoint
before and 8 weeks after intervention
Method of measurement
Enzymatic chlorometric method

Secondary outcomes

1

Description
Waist to hip ratio
Timepoint
before and 8 weeks after intervention
Method of measurement
Inelastic tape without putting pressure on the body

2

Description
Body mass index
Timepoint
before and 8 weeks after intervention
Method of measurement
The ratio of weight in kilograms by the square of height in meters

3

Description
systolic and diastolic blood pressure
Timepoint
before and 8 weeks after intervention
Method of measurement
Sphygmomanometer

Intervention groups

1

Description
Intervention group: Black Seed Oil, 1000 mg capsule, once a day for 8 weeks.
Category
Treatment - Other

2

Description
Control group: paraffin oil, 1000 mg capsule, once a day for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastro intestinal clinic of Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Rashidmayvan
Street address
Department of Gasteroenterology, Imam Khomeini Hospital, Azadegan Ave
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr Nader Saki, Deputy of research development
Street address
Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences, Golestan Ave.
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Ahvaz
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 of Ahvaz Jundishapur 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
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad rashidmayvan
Position

MSc student of Nutrition

Other areas of specialty/work

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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