

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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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+98 61 3161

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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 alcoholic 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 alcoholic 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(triglycid,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 Gastroenterology, 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

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Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences, Golestan Ave.

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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

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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PhD in nutrition science

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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