

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the effect of sesame oil consumption on liver functionality, metabolic syndrome characteristics, insulin resistance, oxidative stress, inflammation and ultrasound findings in women with non-alcoholic fatty liver

Protocol summary

Study aim

Evaluation of the effect of sesame oil consumption on liver functionality, metabolic syndrome characteristics, insulin resistance, oxidative stress, inflammation and ultrasound findings in women with non-alcoholic fatty liver

Design

This study is a randomized, parallel, double-blind clinical trial in which 56 patients with non-alcoholic fatty liver were divided into two groups: sesame oil recipient (n = 28) and sunflower oil recipient (n = 28). For randomization, the stratified randomized permuted block method will be used by using a random number table.

Settings and conduct

In this study, 56 people with non-alcoholic fatty liver from Imam Hossein Hospital in Shahrood will be included in the study. Individuals will be randomly divided into control and intervention groups, respectively. Individuals in the intervention group will consume 30 grams of sesame oil and in the control group 30 grams of sunflower oil for 12 weeks. Blinding of oils is done by a third party who is not aware of the objectives of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female, Being 20 to 50 years old, Having Non-alcoholic fatty liver disease, Routine consumption of sunflower oil, Body mass index between 25 and 40. Exclusion criteria: Smoking, Being menopausal, Having a history of breast cancer, Insulin consumption, Having other liver diseases except non-alcoholic fatty liver, Consumption of hepatotoxicity drugs, Alcohol consumption, Pregnancy, Lactation, Having hormone-dependent cysts.

Intervention groups

Consume 30 grams of sesame oil for 12 weeks in the intervention group and consume 30 grams of sunflower

oil for 12 weeks in the control group

Main outcome variables

Liver enzymes, blood pressure, anthropometric indices, fasting blood sugar, lipid profile, insulin resistance, oxidative stress and inflammation indices, severity of fatty liver

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140208016529N6**

Registration date: **2020-12-12, 1399/09/22**

Registration timing: **prospective**

Last update: **2020-12-12, 1399/09/22**

Update count: **0**

Registration date

2020-12-12, 1399/09/22

Registrant information

Name

Mohammad hassan Entezari

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of sesame oil consumption on liver functionality, metabolic syndrome characteristics, insulin resistance, oxidative stress, inflammation and ultrasound findings in women with non-alcoholic fatty liver

Public title

Effect of sesame oil in treatment of non-alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in the study Female Being 20 to 50 years old Having Non-alcoholic fatty liver disease Routine consumption of sunflower oil Body mass index between 25 and 40

Exclusion criteria:

Participate in other studies in the last 6 months Having weight loss plans in the last three months Having a special diet in the last three months Smoking Being menopausal Having a history of breast cancer Insulin consumption Having allergies Having other liver diseases except non-alcoholic fatty liver Having hereditary hemochromatosis Having serious diseases such as cancer, cholangitis sclerosis, kidney failure, autoimmunity, malignancies, celiac disease Consumption of mineral multivitamin and omega-3 supplements in the past month Consumption of drugs that effects on the level of liver enzymes of ALP, AST and ALT Consumption of drugs that cause fatty liver Using hepatotoxicity drugs Alcohol consumption Pregnancy Lactation Having hormone-dependent cysts Having Wilson's disease

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

A stratified randomized permuted block(with block size 4) will be generated by an independent bio-statistician. Random assignment will be done by the use of a table of random numbers. The participant's enrollment and assignment to the groups will be carried out by a trained nutritionist. Researchers will not be informed about the randomization process until the end of the statistical analysis (allocation concealment)

Blinding (investigator's opinion)

Double blinded

Blinding description

The blinding of the oils is done by a third party who is not aware of the objectives of the study. The oils are poured into opaque bottles with the same labels. Patients and researchers will not be aware of which oils are inside the bottles until the end of the trial.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Esfahan University of Medical Sciences

Street address

Hezar Jerib Street

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Postal code

81746-73461

Approval date

2020-11-09, 1399/08/19

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.548

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

Fatty liver grade

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Liver sonography

Secondary outcomes

1

Description

Blood level of low-density lipoprotein cholesterol

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Medical laboratory (kit)

2

Description

Blood level of triglyceride

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Medical laboratory (kit)

3

Description

Blood level of high-density lipoprotein cholesterol

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Medical laboratory (kit)

4

Description

Blood level of total cholesterol

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Medical laboratory (kit)

5

Description

Anthropometric indicators

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Medical laboratory (kit)

6

Description

Blood pressure

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Medical laboratory (kit)

7

Description

Blood level of insulin

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Medical laboratory (kit)

8

Description

Blood level of C-Reactive Protein

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Medical laboratory (kit)

9

Description

Blood level of Malondialdehyde

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Medical laboratory (kit)

10

Description

Blood level of Fasting Blood Sugar

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Medical laboratory (kit)

11

Description

Blood level of Alanine Aminotransferase

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Medical laboratory (kit)

12

Description

Blood level of Aspartate transaminase

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Medical laboratory (kit)

13

Description

Blood level of Alkaline phosphatase

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Medical laboratory (kit)

Intervention groups

1

Description

Intervention group: The intervention group includes 28 patients. They are randomly placed in this group. They receive 30 grams of sesame oil daily for 12 weeks. The weight loss diet is written for each person, so that 500 calories are deducted from the calculated energy. Calibrated scales are given to them for accurate oil consumption. At the beginning and end of the study, the desired outcomes will be measured.

Category

Treatment - Other

2

Description

Control group: The control group includes 28 patients. They are randomly placed in this group. They receive 30 grams of sunflower oil daily for 12 weeks. The weight loss diet is written for each person, so that 500 calories are deducted from the calculated energy. Calibrated scales are given to them for accurate oil consumption. At the beginning and end of the study, the desired outcomes will be measured.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital of Sharood

Full name of responsible person

Dr. Mohammad Hassan Entezari

Street address

Imam Street

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Semnan

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoi Javanmard

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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

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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

Esfahan University of Medical Sciences

Full name of responsible person

Masoumeh Atefi

Position

student

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hassan Entezari

Position

Specialist in nutrition and diet therapy

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hassan Entezari

Position

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Latest degree

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Other areas of specialty/work

Nutrition

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Major part of information will be available for population.

When the data will become available and for how long

12 months after publication

To whom data/document is available

Available for people working in academic institutions

Under which criteria data/document could be used

To conduct similar studies

From where data/document is obtainable

entezari@hlth.mui.ac.ir

What processes are involved for a request to access data/document

The data will be sent as soon as possible, after receiving the request

Comments