Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 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

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Mohammad hassan Entezari
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Isfahan university of medical sciences
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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 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
City
Isfahan
Province
Isfehan
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
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Web page address
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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
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Masoumeh Atefi
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student
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Person responsible for scientific inquiries

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Dr. Mohammad Hassan Entezari
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Person responsible for updating data

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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