Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the Combined Effects of Flaxseed Consumption and Fasting Mimicking Diet (FMD) on Anthropometric Indices, Blood Lipid Composition, Glycemic Control, Inflammatory Markers, Steatosis and Hepatic Fibrosis in Patients with Non-Alcoholic Fatty Liver Diseases (NAFLD): a Randomized Control Trial

Protocol summary

Study aim

Determine the Effects of Flaxseed Consumption and Fasting Mimicking Diet on Patients with Non-Alcoholic Fatty Liver Diseases

Design

This research is a randomized clinical trial.

Settings and conduct

People were selected from those who were referred to the medical centers who had the conditions to enter the study, and after performing the fibroscan test and receiving consent from them, the people were randomly divided into four groups. At the beginning and end of the study, the desired questionnaires and blood samples will be received.

Participants/Inclusion and exclusion criteria

Entry conditions: age over 18 years, with evidence of non-alcoholic steatohepatitis with a Controlled Attenuation Parameter score above 263, without chronic inflammatory disease; body mass index above 25. Conditions of non-entry: history of cancer, kidney disease, diabetes, cardiovascular diseases and digestive disorders affecting absorption, weight loss of more than 8% in the last 6 months and history of drug and alcohol use and hepatotoxic drugs.

Intervention groups

1- Control. 2- 16:8 fasting-mimicking diet: 16 hours a day in a fasting-mimicking mode and 8 hours of the usual diet. 3- Consumption of flaxseed (30 gr/day). 4- 16:8 fasting-mimicking diet + flaxseed consumption

Main outcome variables

Serum triglycerides Total serum cholesterol Serum LDL-C Serum HDL-C Serum ALT Serum GGT Serum AST Serum hs-CRP Hepatic steatosis The extent of liver fibrosis blood pressure serum glucose Serum insulin Insulin resistance (HOMA-IR) HbA1C Quantitative index of insulin sensitivity(QUICKI) Anthropometric indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100524004010N36**
Registration date: **2023-03-14, 1401/12/23**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-14, 1401/12/23**
Update count: **0**

Registration date

2023-03-14, 1401/12/23

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

2023-03-12, 1401/12/21

Expected recruitment end date
2023-06-11, 1402/03/21
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Combined Effects of Flaxseed Consumption and Fasting Mimicking Diet (FMD) on Anthropometric Indices, Blood Lipid Composition, Glycemic Control, Inflammatory Markers, Steatosis and Hepatic Fibrosis in Patients with Non-Alcoholic Fatty Liver Diseases (NAFLD): a Randomized Control Trial

Public title
Evaluation of the Combined Effects of Flaxseed Consumption and Fasting Mimicking Diet (FMD) on Patients with Non-Alcoholic Fatty Liver Diseases (NAFLD): a Randomized Control Trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Having evidence of non-alcoholic steatohepatitis and CAP score over 263 Not having a history of alcohol and drug abuse Absence of other chronic and acute liver disorders No use of chemical and herbal medicines that affect the liver and weight Not having a chronic inflammatory disease and no history of cancer No treatment with anti-inflammatory drugs, corticosteroids and hormones Not having lost more than 8 percent of the weight in the last 6 months Blood pressure less than 140/90 mmHg Not having uncontrolled kidney disease, pituitary disorders, thyroid, cardiovascular diseases, diabetes and digestive system disorders that affect absorption No history of excessive consumption of flaxseed Not having clinically diagnosed psychiatric disorders that impair the patient's ability to provide written informed consent Willingness to participate in the study
Exclusion criteria:
Having clinically diagnosed psychiatric disorders that impair the patient's ability to provide written informed consent Use of other supplements Unwillingness to participate in the study
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 100 patients with non-alcoholic fatty liver, over 18 years of age, were randomized for 12 weeks by the simple randomized method according to the table of four random numbers and after stratification for BMI (1- range 25 to 29 and 2 - 30 and above) in four groups: 1- Control (nutritional recommendations to control the disease) 2- 16:8 fasting-mimicking diet: 16 hours a day in a fasting-mimicking mode and 8 hours of the usual diet. 3- Consumption of flaxseed (nutritional recommendations for disease control) 4- 16:8 fasting-mimicking diet + flaxseed consumption: 16 hours a day in a fasting-mimicking mode and 8 hours of usual diet plus the consumption of flaxseed.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not 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 (NNFTRI)
Street address
#7, Shahid Hafezi Ave, Farahzadi Blvd, Shahrak Gharb
City
Tehran
Province
Tehran
Postal code
1981619573
Approval date
2023-03-11, 1401/12/20
Ethics committee reference number
IR.SBMU.NNFTRI.REC.1401.070

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
Level of steatosis and liver fibrosis
Timepoint
At the beginning and 3 months after the start of the study
Method of measurement
Fibroscan

Secondary outcomes

1

Description
lipid profile
Timepoint
At the beginning of the study and at the end of the study (after 3 months)
Method of measurement
blood sample

2

Description
insulin sensitivity index
Timepoint
At the beginning of the study and at the end of the study (after 3 months)
Method of measurement
math formula

3

Description
Insulin resistance index
Timepoint
At the beginning of the study and at the end of the study (after 3 months)
Method of measurement
math formula

4

Description
Insulin concentration
Timepoint
At the beginning of the study and at the end of the study (after 3 months)
Method of measurement
blood sample

5

Description
Anthropometric indices
Timepoint
At the beginning of the study and at the end of the study (after 3 months)
Method of measurement
Tape measure, scale and mathematical formula

6

Description
blood pressure
Timepoint
At the beginning of the study and at the end of the study (after 3 months)
Method of measurement
Sphygmomanometer

7

Description
high-sensitivity C-reactive protein
Timepoint
At the beginning of the study and at the end of the study (after 3 months)
Method of measurement
blood sample

8

Description
Liver enzymes alanine transaminase, aspartate aminotransferase,gamma-glutamyl tansferase
Timepoint
At the beginning of the study and at the end of the study (after 3 months)
Method of measurement
blood sample

9

Description
Serum glucose concentration
Timepoint
At the beginning of the study and at the end of the study (after 3 months)
Method of measurement
blood sample

10

Description
HbA1C
Timepoint
At the beginning of the study and at the end of the study (after 3 months)
Method of measurement
blood sample

Intervention groups

1

Description
The first intervention group: (Fasting mimicking diet 16/8): the people were given nutritional recommendations to control the disease and a person is in a fasting mimicking mode for 16 hours a day.
Category
N/A

2

Description
The second intervention group (consumption of flaxseed): the people were given nutritional recommendations to control the disease and they consumed 30 grams of flaxseed daily in 8 hours that are not fast.

Category
N/A

3

Description
The third intervention group (fasting mimicking diet 16/8 + flaxseed consumption): the people were given nutritional recommendations to control the disease, and the person was in a fasting mimicking mode for 16 hours a day and 8 hours of the usual diet plus the consumption of flaxseeds.

Category
N/A

4

Description
Control group: They follow the nutritional recommendations to control the disease.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani General Hospital

Full name of responsible person
Amir Sadeghi

Street address
Ayatollah Taleghani Educational Hospital, Araabi St.,Yaman Ave, Chamran Highway,Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Azita Hekmatdoost

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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

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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Azita Hekmatdoost

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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