

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)

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#7, Shahid Hafezi Ave, Farahzadi Blvd, Shahrak Gharb

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Province

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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 transferase

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Hekmatdoost

Street 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

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

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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