

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of effect of flaxseed oil on the non invasive liver marker's in patients with nonalcoholic fatty liver disease and comparison with placebo

Protocol summary

Study aim

Evaluation of effect of flaxseed oil on the non invasive liver marker's in patients with nonalcoholic fatty liver disease and comparison with placebo

Design

A clinical trial with one intervention group and one control group, with parallel groups, double-blind, randomized with Random number table, phase 3 on 60 patients

Settings and conduct

After obtaining informed consent, patients are randomly divided into intervention and placebo groups. flaxseed oil in intervention group and placebo in control group prescribed in a dose of 1g 2 times a day for 2 months. Demographic information of patients will be recorded. The study will perform at Qaim Hospital in a double-blind manner of patient and outcome assessor

Participants/Inclusion and exclusion criteria

Entry Conditions: Patient satisfaction AST and ALT level at least 1/5 times normal with ultrasound confirmation of fatty liver Age: 15 to 60 Non-entry conditions: Consumption or history of alcohol consumption Positive serology of viral hepatitis (C, B) ANA or AMA, alpha 1 antitrypsin positive test, low serum ceruloplasmin level or high level of ASMA and LKM14 antibodies Ferritin above 450 or 45% IRON / TIBC > 5 The patient develops an acute or chronic illness before or during the intervention that interferes with LFT (liver function tests) The patient take a drug before or during the intervention that has the potential to interfere with LFT Age less than 15 years and more than 60 years Pregnancy Taking herbal medicine

Intervention groups

In the intervention group, flaxseed oil is prescribed in a dose of 1g 2 times a day for 2 months. In the control group, placebo is prescribed in a dose of 1g 2 times a day for 2 months.

Main outcome variables

Primary variables: AST, ALT, ALP, BILLI TOTAL AND DIRECT, Secondary variables: FBS, weight, height, Abdominal circumference, TG, CHOLESTROL, LDL, HDL, BMI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220521054947N1**

Registration date: **2022-08-12, 1401/05/21**

Registration timing: **prospective**

Last update: **2022-08-12, 1401/05/21**

Update count: **0**

Registration date

2022-08-12, 1401/05/21

Registrant information

Name

Delaram Omidvar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3603 0348

Email address

omidvard971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-16, 1401/05/25

Expected recruitment end date

2022-11-16, 1401/08/25

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of effect of flaxseed oil on the non invasive liver marker's in patients with nonalcoholic fatty liver disease and comparison with placebo

Public title
Evaluation of effect of flaxseed oil on the non invasive liver marker's in patients with nonalcoholic fatty liver disease and comparison with placebo

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patient satisfaction AST and ALT level at least 1/5 times normal with ultrasound confirmation of fatty liver Age: 15 to 60
Exclusion criteria:
 Consumption or history of alcohol consumption Positive serology of viral hepatitis (C, B) ANA or AMA, alpha 1 antitrypsin positive test, low serum ceruloplasmin level or high level of ASMA and LKM14 antibodies Ferritin above 450 or 45% IRON / TIBC> 5 The patient develops an acute or chronic illness before or during the intervention that interferes with LFT (liver function tests) The patient take a drug before or during the intervention that has the potential to interfere with LFT Age less than 15 years and more than 60 years Pregnancy Taking herbal medicine

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization with a table of random numbers using www.sealedenvelope.com In this method, a set of random numbers is generated and placed in a table. First, determine the direction of reading the numbers in the table. A numerical group is assigned to each intervention and control group. Then we choose a random number and move in the specified direction and record the numbers and assign them to different groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Double-blind randomization of the subjects and outcome assessor by sealed envelopes. some envelopes will be prepared and each of the random sequences will be

recorded on a card and the cards will be placed inside the envelopes. In order to preserve the random sequence, the pass number will be written on the outer surface of the envelopes in the same way. Finally, the envelopes will be sealed and placed inside the boxes. At the time of registration of the companies, according to the order of entry of qualified companies into the study, one of the envelopes will be opened and the allocated group of that participant will be revealed.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Azadi Square, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2022-04-12, 1401/01/23

Ethics committee reference number

IR.mums.medical.rec.1401.045

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Other specified inflammatory liver diseases

Primary outcomes

1

Description

AST level changes

Timepoint

AST level measurement at baseline and at week 8

Method of measurement

blood sample

2

Description

ALT level changes

Timepoint

ALT level measurement at baseline and at week 8

Method of measurement

blood sample

3

Description

ALP level changes

Timepoint

ALP level measurement at baseline and at week 8

Method of measurement

blood sample

4

Description

Bilirubin total and direct level changes

Timepoint

Bilirubin total and direct level measurement at baseline and at week 8

Method of measurement

blood sample

Secondary outcomes

1

Description

Fasting Blood Sugar

Timepoint

at baseline and at week 8

Method of measurement

blood sample

2

Description

Weight

Timepoint

at baseline and at week 8

Method of measurement

Weighing scale

3

Description

Height

Timepoint

at baseline and at week 8

Method of measurement

Meter

4

Description

High-density lipoprotein (HDL)

Timepoint

at baseline and at week 8

Method of measurement

Blood sample

5

Description

Low-density lipoprotein (LDL)

Timepoint

at baseline and at week 8

Method of measurement

Blood sample

6

Description

Cholesterol

Timepoint

at baseline and at week 8

Method of measurement

Blood sample

7

Description

Triglyceride

Timepoint

at baseline and at week 8

Method of measurement

Blood sample

8

Description

Body mass index (BMI)

Timepoint

at baseline and at week 8

Method of measurement

Body weight (kg) divided by the square of the body height(m)

Intervention groups

1

Description

Intervention group: In the intervention group, flaxseed oil capsules made by Barij Essense Company is prescribed in a dose of 1g 2 times a day for 2 months (one capsule two times a day).

Category

Treatment - Drugs

2

Description

Control group: In the control group, placebo capsules made by Barij Essense Company is prescribed in a dose of 1g 2 times a day for 2 months (one capsule two times a day).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Sahar Ravanshad

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Ahmadabad Boulevard, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ghayour Mobarhan

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Delaram Omidvar

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Medical doctor

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data obtained in the study can be shared after making the participants unrecognizable.

When the data will become available and for how long

After publishing the results, it will be possible to access the data.

To whom data/document is available

The data will be available to medical researchers.

Under which criteria data/document could be used

The use of data is unrestricted if it is not subject to plagiarism.

From where data/document is obtainable

researchers can ask Dr. Delaram Omidvar to receive the data.

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

The esteemed applicant must inform the above mentioned researcher of his / her details and the reason for the need for the data. After consulting with other researchers, He will announce his agreement or disagreement.

Comments