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 intrvention 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 ceruloplasin 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 ceruloplasin 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
Street address
Ahmadabad Boulevard, Mashhad
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9176999311
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Email
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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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

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Position
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Person responsible for updating data

Contact

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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