Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative effects of flaxseed oil and vitamin E on non-invasive markers of liver in patients with nonalcoholic fatty liver disease.

Protocol summary

Summary

Objectives: Prescribing Flaxseed oil on the non invasive liver marker's in patients with non-alcoholic fatty liver disease. Design: Interventional- Not blinded. The major inclusion criteria are: The enzyme Aspartate Aminotransferase (AST) and Alanine Aminotransferase (ALT) at least 1.5 times above the normal limit, confirmed by the kidney sonography; Meeting at least one of the following criteria: Within the age range of 15-60 years old, diabetes, Hyperlipidemia, and Obesity. The major exclusion criteria are as follows: Consuming alcohol or having a history of drinking problems; Positive serology for viral hepatitis (C , B); Positive Anti-Nuclear Antibody (ANA) or Anti-Mitochondrial Antibodies (AMA) tests, Alpha-1 antitrypsin; Reduced serum levels of ceruloplasmin or increasing levels of Anti-smooth muscle (ASMA) and Liver kidney microsomal type 1 antibody (LKM1) antibodies; Ferritin level larger than 450, or Iron and Total iron binding capacity (IRON/TIBC) less than 45%; The patients being diagnosed with acute or chronic illnesses which cause disorders in LFT (liver function tests), before or during the medical intervention; the patients' consumption of drugs, before or during the medical intervention, which cause disorders in LFT; Pregnancy; Age less than 15 or above 60 years. Target sample size: 60 people Intervention group: Oral Flaxseed every day 3 times (1 gr) for 2 months; Control group: Oral E Vitamin 3 times a day for 2 months. Main outcome measure: Liver Enzyme (at the admission and 2 months after applying the intervention).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111715427N1**
Registration date: **2014-01-21, 1392/11/01**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-01-21, 1392/11/01

Registrant information

Name
Ali Beheshti Namdar
Name of organization / entity
Imam Reza Hospital
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Mashhad University of Medical Medicine

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effects of flaxseed oil and vitamin E on non-invasive markers of liver in patients with nonalcoholic fatty liver disease.

Public title

Comparative effects of flaxseed oil and vitamin E on non-invasive markers of liver in patients with nonalcoholic

fatty liver disease.

Purpose

Treatment

Inclusion/Exclusion criteria

The major inclusion criteria are: The enzyme Aspartate Aminotransferase (AST) and Alanine Aminotransferase (ALT) at least 1.5 times above the normal limit, confirmed by the kidney sonography; Meeting at least one of the following criteria: Within the age range of 15-60 years old, diabetes, Hyperlipidemia, and Obesity. The major exclusion criteria are as follows: Consuming alcohol or having a history of drinking problems; Positive serology for viral hepatitis (C , B); Positive Anti-Nuclear Antibody (ANA) or Anti-Mitochondrial Antibodies (AMA) tests, Alpha-1 antitrypsin; Reduced serum levels of ceruloplasmin or increasing levels of Anti-smooth muscle (ASMA) and Liver kidney microsomal type 1 antibody (LKM1) antibodies; Ferritin level larger than 450, or Iron and Total iron binding capacity IRON/TIBC less than 45%; The patients being diagnosed with acute or chronic illnesses which cause disorders in LFT (liver function tests), before or during the medical intervention; the patients' consumption of drugs, before or during the medical intervention, which cause disorders in LFT; Pregnancy; Age less than 15 or above 60 years.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

the patients are randomly (and equally) divided into two groups, based on the table of random numbers; one group is administered Flaxseed oil and the other receives E vitamin

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Mashhad University of Medical Sciences

Street address

Vice Chancellor for research of Mahhad University of Medical Sciences, Daneshgah Street, Ghoreishi Building, Mashhad

City

Mashhad

Postal code

Approval date

2013-02-20, 1391/12/02

Ethics committee reference number

910677/1/24

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description

Nonalcoholic fatty liver disease

Primary outcomes

1

Description

Liver Enzyme

Timepoint

Admission and 2 months after applying the intervention

Method of measurement

Blood Sampling

Secondary outcomes

1

Description

Blood Glucose

Timepoint

Admission and 2 months after applying the intervention

Method of measurement

Blood Sampling

Intervention groups

1

Description

Intervention group: Oral Flaxseed every day 3 times (1 gr) for 2 months

Category

Treatment - Drugs

2

Description

Control group: E Vitamin, Oral capsule, 3 times a day for 2 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology Clinic of Imam Reza Hospital
Full name of responsible person
Ali Beheshti Namdar
Street address
Imam Reza Hospital, Imam Reza Square, Ebnesina Street, Mashhad
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2

Recruitment center
Name of recruitment center
Gastroenterology Clinic of GHAEM Hospital
Full name of responsible person
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Ghaem Hospital, Ahmadabad Street, Mashhad
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Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Mashhad University of Medical Sciences
Full name of responsible person
Mohammad Ramezani
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City
Mashhad
Grant name
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty