

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 2026

The effect of oral alpha-lipoic acid supplement on nutritional status and serum levels of metabolic, oxidative, inflammatory indicators and serum cytokeratin-18 in nonalcoholic fatty liver disease patients

Protocol summary

Summary

This randomized double blind placebo controlled trial study design with aim to determine the effect of oral alpha-lipoic acid supplement on nutritional status and serum levels of metabolic, oxidative, inflammatory indicators and serum cytokeratin-18 in nonalcoholic fatty liver disease patients (NAFLD) receiving 400IU vitamin E. According to inclusion and exclusion criteria, 44 patients with NAFLD will be recruited to the study. Informed written consent form and personality questionnaire will be filled for all of the patients. Participants will be randomly allocated to intervention and control groups using blocked randomization method. Subjects in Intervention and control group will receive 2 capsules alpha-lipoic acid (each containing 600mg, daily 1200mg) or 4 capsules of placebo, respectively for 12 weeks. Anthropometric measurements including weight, height, waist circumference and body mass index (BMI) will be evaluated on baseline and again after the intervention. Furthermore, dietary intake and physical activity status will be determined by 3-day 24-hours food recall questionnaire (one for the weekend and two for weekdays) and physical activity record at baseline and at the end of weeks 6 and 12.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201511143320N12**
Registration date: **2015-12-24, 1394/10/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-24, 1394/10/03

Registrant information

Name

Mehrangiz Ebrahimi mamagani

Name of organization / entity

Health & Nutrition faculty of Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 1113

Email address

ebrahimimamagani@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Nutrition Research Center, Tabriz University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral alpha-lipoic acid supplement on nutritional status and serum levels of metabolic, oxidative, inflammatory indicators and serum cytokeratin-18 in nonalcoholic fatty liver disease patients

Public title

The effect of oral alpha-lipoic acid supplement on nonalcoholic fatty liver disease patients

Purpose

Supportive

Inclusion/Exclusion criteria
 Inclusion criteria: Desire to participate in the study, confirmation of NAFLD with liver Ultrasonography, aged 20-50 years from both gender, body mass index between 30-40 kg/m², taking 400IU/day vitamin E, moderate physical activity level
 Exclusion criteria: Alcohol consumption, smoking, pregnant, lactating and menopausal women, very active subjects or athletes, hospitalized subjects, suffering from hypertension, cardiovascular diseases, pulmonary diseases, renal diseases, liver transplantation, other acute and chronic liver diseases, biliary system disorders, cancer, Inherited disorders affecting the liver. Receiving Oral Contraceptive Pill (OCP) and antioxidant vitamins unless vitamin E, hypertension and thyroid affecting drugs, statins, inflammation and Insulin sensitivity affecting drugs and Hepatotoxic drugs including phenytoin, amiodarone, levothyroxine, tamoxifen and lithium

Age
 From **20 years** old to **50 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **44**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee
 The Research Ethics Committee of Tabriz University of Medical Sciences

Street address
 Attar Neyshabori Street, Tabriz University of Medical Sciences

City
 Tabriz

Postal code

Approval date
 2015-12-09, 1394/09/18

Ethics committee reference number

TBZMED.REC.1394.786

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver disease

ICD-10 code

K 76

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Hepatic steatosis

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Ultrasound of liver

2

Description

Liver enzymes (ALP, ALT, AST)

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Serum concentration of these enzymes with enzymatic method by kits

3

Description

Fasting Blood Sugar (F.B.S.)

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Enzymatic method

4

Description

Serum insulin level

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Chemoluminescence

5

Description

Insulin resistance

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Calculation of HOMA-IR

6

Description

Lipid profile

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Triglyceride, total cholesterol and HDL-cholesterol with spectrophotometry and LDL-cholesterol with Friedewald equation

7

Description

Oxidative indicators

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Total antioxidant capacity (TAC) by using spectrophotometry, MDA by using thiobarbituric acid, SOD and GPX activities by using ELIZA kits

8

Description

Inflammatory indicators

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Serum levels of TNF- α , TGF- β and IL-10 by using ELIZA kits

9

Description

Sirtuin-1

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

ELIZA kit

10

Description

Fetuin-A

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

ELIZA kit

11

Description

Cytokeratin-18

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

ELIZA kit

12

Description

Added at 2016-01-05: Serum Ferritin

Timepoint

Added at 2016-01-05: Baseline and 12 weeks after intervention

Method of measurement

Added at 2016-01-05: ELIZA kit

13

Description

Added at 2016-01-05: Serum Adiponectin

Timepoint

Added at 2016-01-05: Baseline and 12 weeks after intervention

Method of measurement

Added at 2016-01-05: ELIZA kit

14

Description

Added at 2016-01-05: Serum MCP-1 (Monocyte chemoattractant protein-1

Timepoint

Added at 2016-01-05: Baseline and 12 weeks after intervention

Method of measurement

Added at 2016-01-05: ELIZA kit

15

Description

Added at 2016-01-05: Serum IL-6

Timepoint

Added at 2016-01-05: Baseline and 12 weeks after intervention

Method of measurement

Added at 2016-01-05: ELIZA kit

16

Description

Added at 2016-10-29: Irisin

Timepoint

Added at 2016-10-29: Baseline and 12 weeks after intervention

Method of measurement

Added at 2016-10-29: ELIZA kit

17

Description

Added at 2016-10-29: Plasminogen Activator Inhibitor Factor - 1 (PAI-1

Timepoint

Added at 2016-10-29: Baseline and 12 weeks after intervention

Method of measurement

Added at 2016-10-29: ELIZA kit

18

Description

Added at 2016-10-29: Leptin

Timepoint

Added at 2016-10-29: Baseline and 12 weeks after

intervention

Method of measurement

Added at 2016-10-29: ELIZA kit

Secondary outcomes

1

Description

Anthropometric measurements

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Weight and Height by using Seca scale and stadiometer respectively, waist circumference by using tape measure, Body mass index (BMI) will be calculated as weight in kilograms divided by the square of height in meters

2

Description

Energy and macro-nutrients intake

Timepoint

Baseline, 6 and 12 weeks after intervention

Method of measurement

3-day 24 hours food recall

3

Description

Physical activity level

Timepoint

Baseline, 6 and 12 weeks after intervention

Method of measurement

International physical activity questionnaire

4

Description

Added at 2016-01-05: Body composition (Total body fat, visceral body fat, body water, body bone mass and body muscle mass percentages

Timepoint

Added at 2016-01-05: Baseline and 12 weeks after intervention

Method of measurement

Added at 2016-01-05: Bioelectrical impedance analysis machine

5

Description

Added at 2016-10-29: Appetite status

Timepoint

Added at 2016-10-29: Baseline and 12 weeks after intervention

Method of measurement

Added at 2016-10-29: Visual Analogue Scales questionnaire

6

Description

Added at 2016-10-29: Subcutaneous abdominal fat thickness

Timepoint

Added at 2016-10-29: Baseline and 12 weeks after intervention

Method of measurement

Added at 2016-10-29: Ultrasonography

Intervention groups

1

Description

Intervention group: Daily Oral consumption of 2 capsule contain 600 mg alpha-lipoic acid supplement

Category

Other

2

Description

Control group: Daily Oral consumption of 2 capsule contain 600 mg placebo

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheykholrais clinic

Full name of responsible person

Dr. Mehrangiz Ebrahimi Mamagani

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nutrition Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Alireza Ostadrahimi

Street address

Nutrition Faculty, Attarneyshabouri street, Golgasht street, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Nutrition Research Center, Tabriz 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****Name of organization / entity**

Nutrition Faculty, Tabriz University of Medical Sciences

Full name of responsible person

Farshad Amirkhizi

Position

Ph.D. candidate in Nutrition

Other areas of specialty/work**Street address**

Nutrition Faculty, Attarnayshabouri street, Golgasht street

City

Tabriz

Postal code**Phone**

+98 41 3335 7581

Fax**Email**

amirkhizif@tbzmad.ac.ir

Web page address

Nutrition Faculty, Attarneyshabouri street, Golgasht street

City

Tabriz

Postal code**Phone**

+98 413335229500

Fax**Email**

ebrahimimamagani@tbzmed.ac.ir

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

Nutrition Faculty, Tabriz University of Medical Sciences

Full name of responsible person

Farshad Amirkhizi

Position

Ph.D. Candidate in Nutrition

Other areas of specialty/work**Street address**

Nutrition Faculty, Attarneyshabouri street, Golgasht street

City

Tabriz

Postal code**Phone**

+98 41 3335 7581

Fax**Email**

amirkhizif@tbzmed.ac.ir

Web page address**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

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Nutrition Faculty, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mehrangiz Ebrahimi Mamagani

Position

Ph.D. of Nutrition

Other areas of specialty/work**Street address**