Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 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

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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 subjectes 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

Chemoluminescense

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 Scienses

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 Scienses
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

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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