Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

The Effect of coenzyme Q10 on serum concentrations of pentraxin 3 and metabolic parameters in non-alcoholic fatty liver disease

Protocol summary

Summary

The present study is a double-blind, placebo-controlled, randomized trial to investigate the effect of coenzyme Q10 on serum concentrations of pentraxin 3 and metabolic parameters in patients with non-alcoholic fatty liver disease (NAFLD). 44 patients with non-alcoholic fatty liver attending the Azadi clinic will be recruited and randomly assigned to receive either the intervention or the placebo. The main inclusion criteria: women aged 20-50 years (premenopausal) and in men 20-65 years and patients newly diagnosed. The main exclusion criteria: any cause of chronic liver disease other than NAFLD; suffering from gastrointestinal disease, diabetes, rheumatoid arthritis, heart failure and renal disease; receiving supplements of vitamins, antioxidants, fiber and omega-3 within 3 weeks before baseline and during the study and using drugs with liver complications. Treatment group will receive one 100 milligram capsule coenzyme Q10 per day and placebo group will receive placebo capsules containing starch for 4 weeks. At baseline and at the endpoint of the study, weight and height will be measured and BMI will be calculated and dietary intake of the participants will be evaluated by 3 dietary record questionnaires. Biochemical variables including plasma level of aspartat aminotransferase, alanine aminotransferase, total cholesterol, triglycerides, high density lipoprotein, low density lipoprotein, fasting blood glucose, insulin resistance, pentraxin 3 will be measured using the appropriate techniques at baseline and endpoint of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305254105N12**
Registration date: **2013-06-15, 1392/03/25**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-06-15, 1392/03/25

Registrant information

Name
Beit Allah Alipour
Name of organization / entity
Health & Nutrition Faculty
Country
Iran (Islamic Republic of)
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+98 41 1335 7580
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alipourb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-08-22, 1392/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of coenzyme Q10 on serum concentrations of pentraxin 3 and metabolic parameters in non-alcoholic fatty liver disease

Public title

The Effect of coenzyme Q10 on serum concentrations of pentraxin 3 and metabolic parameters in non-alcoholic

fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who agree to participate in the study; Women aged 20-50 years (premenopausal) and in men 20-65 years; Patients newly diagnosed. Exclusion criteria: Alcohol intake; Any cause of chronic liver disease other than NAFLD, such as testing positive for hepatitis B, hepatitis C and autoimmune hepatitis – Immune; Suffering from gastrointestinal disease, diabetes and rheumatoid arthritis; Presence of inherited Hemochromatosis (transferrin saturation greater than 45%) and Wilson's disease; Cholestatic liver disease, advanced liver disease, heart failure, thyroid (abnormal TSH) and renal disease; History of cancer and treatment; Receiving supplements of vitamins (A,C,E), antioxidants, fiber and omega-3 within 3 weeks before baseline and during the study; Drugs such as corticosteroids, amiodarone, tamoxifen, cyclins, perhexiline, methotrexate, aspirin and hydralazine; Presence of pregnancy or lactation or menopause; Taking contraceptive drugs; Liver transplantation; Gastric bypass surgery; Performing a complete intravenous feeding; Rapid weight loss; Cut part of the intestine and gastropathy; Follow the diet and weight loss, Cachexia and Taking anticoagulation.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

2

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

Ethics committee of Tabriz University of medical sciences and health services

Street address

Golgasht St, Azadi Ave

City

Tabriz

Postal code

Approval date

2013-05-13, 1392/02/23

Ethics committee reference number

9237

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver disease

ICD-10 code

K76

ICD-10 code description

Other diseases of liver

Primary outcomes

1

Description

Liver Enzymes(ALT,AST)

Timepoint

At baseine and after 4 weeks of intervention

Method of measurement

Autoanalyzer

2

Description

Total Cholesterol

Timepoint

At baseine and after 4 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Triglyceride

Timepoint

At baseine and after 4 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

HDL

Timepoint

At baseine and after 4 weeks of intervention

Method of measurement

Spectrophotometry

5

Description

LDL

Timepoint
At baseine and after 4 weeks of intervention
Method of measurement
Friedewald Formula

6

Description
Insulin
Timepoint
At baseine and after 4 weeks of intervention
Method of measurement
ELIZA

7

Description
HOMA-IR
Timepoint
At baseine and after 4 weeks of intervention
Method of measurement
Formula

8

Description
Fasting Blood Sugar
Timepoint
At baseine and after 4 weeks of intervention
Method of measurement
Spectrophotometry

9

Description
AST/ALT
Timepoint
At baseine and after 4 weeks of intervention
Method of measurement
Formula

10

Description
Pentraxin 3
Timepoint
At baseine and after 4 weeks of intervention
Method of measurement
ELIZA

Secondary outcomes

1

Description
Food intake
Timepoint
At baseine and after 4 weeks of intervention
Method of measurement
dietary record questionnaire

2

Description
Body Mass Index
Timepoint
At baseine and after 4 weeks of intervention
Method of measurement
Scales and meters

Intervention groups

1

Description
One 100 milligram capsule each day for 4 weeks
Category
Treatment - Drugs

2

Description
One capsule containing starch each day for 4 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Azadi clinic in Tabriz
Full name of responsible person
Elnaz Jafarvand
Street address
Azadi clinic, Azadi Ave
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Alireza Ostadrahimi
Street address
Tabriz University of Medical Science, Golgasht St
City
Tabriz
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, 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz university of medical sciences

Full name of responsible person

Dr. Beitullah Alipour

Position

Associate Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz university of medical sciences

Full name of responsible person

Elnaz Jafarvand

Position

MSc student in Health Sciences in Nutrition

Other areas of specialty/work

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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