

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 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)

###### Phone

+98 41 1335 7580

###### Email address

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 baseline and after 4 weeks of intervention

## **Method of measurement**

Friedewald Formula

## **6**

### **Description**

Insulin

### **Timepoint**

At baseline and after 4 weeks of intervention

### **Method of measurement**

ELIZA

## **7**

### **Description**

HOMA-IR

### **Timepoint**

At baseline and after 4 weeks of intervention

### **Method of measurement**

Formula

## **8**

### **Description**

Fasting Blood Sugar

### **Timepoint**

At baseline and after 4 weeks of intervention

### **Method of measurement**

Spectrophotometry

## **9**

### **Description**

AST/ALT

### **Timepoint**

At baseline and after 4 weeks of intervention

### **Method of measurement**

Formula

## **10**

### **Description**

Pentraxin 3

### **Timepoint**

At baseline and after 4 weeks of intervention

### **Method of measurement**

ELIZA

## **Secondary outcomes**

### **1**

#### **Description**

Food intake

#### **Timepoint**

At baseline and after 4 weeks of intervention

#### **Method of measurement**

dietary record questionnaire

## **2**

### **Description**

Body Mass Index

### **Timepoint**

At baseline 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**

**Street address**

Golgasht Street

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1335 7580

**Fax**

**Email**

alipourb@tbzmed.ac.ir

**Web page address**

**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**

**Street address**

Golgasht Street

**City**

Tabriz

**Postal code**

**Phone**

**Fax**

**Email**

elnazjafarvand@yahoo.com

**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*