

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### The effect of conjugated linoleic acid(CLA) on insulin resistance, lipid profile, oxidative stress, inflammatory factors and resistin in obese patients with Non-alcoholic fatty liver disease (NAFLD) under weight loss diet :A randomized clinical control trial

#### Protocol summary

##### Summary

This randomized double blind controlled trial is designed with the aim to determine the effect of CLA on insulin resistance, lipid profile, oxidative stress, inflammatory factors and resistin in patients with NAFLD. 46 patients with NAFLD will be randomly divided into 2 intervention and control groups with 23 subjects. Subject will receive 3 capsules of CLA (each containing 1000mg, daily 3000mg) with weight loss diet and in the control group, just weight loss diet for eight weeks. The prescribed diet with 700 kcal lost based on the current weight will be considered. For all the participants, personality questionnaire and food frequency questionnaire for food habit evaluation at first of the study, and 3 dietary records for assessment of nutrient intake and 3 physical activity questionnaires at 0,4,8 weeks will be filled. The anthropometric and blood pressure measurements every 2 weeks, and biochemical and body composition measurements at first and end of the study will be done. Liver ultrasound for all participants in the study will be repeated at the end of the study. Therefore the effect of CLA on measured factors could be compared in intervention group with control group.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014020516491N1**

Registration date: **2014-06-09, 1393/03/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-06-09, 1393/03/19

##### Registrant information

###### Name

Mehrangiz Ebrahimimamagani

###### Name of organization / entity

Nutrition faculty, Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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##### Recruitment status

###### Recruitment complete

##### Funding source

Deputy of Research -Tabriz University of Medical Sciences

##### Expected recruitment start date

2014-02-09, 1392/11/20

##### Expected recruitment end date

2014-09-21, 1393/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of conjugated linoleic acid(CLA) on insulin resistance, lipid profile, oxidative stress, inflammatory factors and resistin in obese patients with Non-alcoholic fatty liver disease (NAFLD) under weight loss diet :A randomized clinical control trial

**Public title**

The effect of CLA in patients with Non-alcoholic fatty liver disease.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Verification of having NAFLD (based on liver ultrasound and liver enzyme levels above normal values based on kits used); 20-50 years old; BMI=30-40; taking 400IU vitamin E daily. Exclusion criteria: Consumption of alcohol; Pregnancy or lactation and menopause; being athletic; Inflammatory conditions such as infection; history or perceive of hypertension; Family history of hyperlipidemia; history or perceive of cardiovascular disease; history or perceive of lung disease; history or perceive of renal disease; Liver transplantation; Acute or chronic disorders and other diseases of the liver (hepatitis B, C and liver infections, etc.); Biliary disease; Known Autoimmune disease; Cancer; An inherited disorder affecting the liver status (iron and copper storage disease, etc.); Perceive diseases such as burns and injury during the study; surgery in last 3 months; the use of some medications such as antihypertensives, insulin sensitivity enhancer, hepatotoxic drugs, statines; Taking any vitamins, minerals and antioxidant supplementation in the last two months; Taking contraceptive pills and estrogen; Consumption of flaxseed; consumption of nuts more than 3 per day.

**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: **46**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not 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**

Tabriz University of Medical Sciences, Attar Neyshabori Street -Golgasht Street

**City**

Tabriz

**Postal code****Approval date**

2014-03-03, 1392/12/12

**Ethics committee reference number**

92225

**Health conditions studied****1****Description of health condition studied**

non- alcoholic fatty liver disease

**ICD-10 code**

K76.0

**ICD-10 code description**

Fatty (change of) liver, not elsewhere classified

**Primary outcomes****1****Description**

Resistin

**Timepoint**

Beginning and end of the intervention

**Method of measurement**

Elisa

**2****Description**

Inflammatory factors(IL-6,IL-10,TNFa,hs-CRP)

**Timepoint**

Beginning and end of the study

**Method of measurement**

IL-6,IL-10,TNFa: Elisa and hs-CRP : immunoturbidimetry

**3****Description**

Insulin resistance and Insulin sensitivity

**Timepoint**

Beginning and end of the intervention

**Method of measurement**

Insulin resistance with HOMA-IR index and Insulin sensitivity with Quicki index

**4****Description**

liver enzymes(AST-ALT-ALP)

**Timepoint**

Beginning and end of the intervention

**Method of measurement**

IFCC

## 5

### **Description**

Lipid profile

### **Timepoint**

Beginning and end of the intervention

### **Method of measurement**

Spectrophotometry and Friedewald Formula for LDL

## 6

### **Description**

Oxidative Stress Indices(TAC-ARE-MDA)

### **Timepoint**

Beginning and end of the intervention

### **Method of measurement**

TAC and ARE : spectrophotometry and MDA : thiobarbituric acid

## 7

### **Description**

Sonography findings

### **Timepoint**

Beginning and end of the intervention

### **Method of measurement**

Liver Sonography

## **Secondary outcomes**

## 1

### **Description**

Anthropometry(BMI-WC-WHR-WHtR)

### **Timepoint**

Beginning, second, fourth, sixth and end of the intervention

### **Method of measurement**

metr, scale and stadiometr

## 2

### **Description**

Body composition

### **Timepoint**

Beginning and end of the intervention

### **Method of measurement**

BIA

## 3

### **Description**

Energy and nutrient intake

### **Timepoint**

beginning, fourth week and end of the intervention

### **Method of measurement**

3 day food record

## 4

### **Description**

Comparison of physical activity

### **Timepoint**

beginning, fourth week and end of the intervention

### **Method of measurement**

Physical Activity Questionnaire

## **Intervention groups**

## 1

### **Description**

3 capsules of CLA(each containing 1000mg, daily 3000mg) with weight loss diet for eight weeks in intervention group

### **Category**

Treatment - Drugs

## 2

### **Description**

weight loss diet for eight weeks in control group

### **Category**

Treatment - Other

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Sheykholrais clinic

#### **Full name of responsible person**

Dr. Mehrangiz Ebrahimimamagani

#### **Street address**

Sheykholrais clinic, Azadi street

#### **City**

Tabriz

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Deputy of research, Tabriz University of Medical Sciences

#### **Full name of responsible person**

Mohammadreza Rashidi

#### **Street address**

Tabriz University of Medical Sciences, Attar Neyshabori Street, Golgasht Street

#### **City**

Tabriz

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Deputy of 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****Name of organization / entity**

Deputy of Research, Nutrition faculty, Tabriz  
University of Medical Sciences

**Full name of responsible person**

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**Position**

Nutrition, PhD

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Nutrition Faculty, Tabriz University of Medical  
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**Full name of responsible person**

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Master Science Student of Public Health Nutrition

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**Position**

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

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Street

**City****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*