

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

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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

Dr. Mehrangiz Ebrahimimamagani

Position

Nutrition, PhD

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Full name of responsible person

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Master Science Student of Public Health Nutrition

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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