Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Oct 2026

The effect of conjugated linoleic acid(CLA) on insulin resitsance, 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 resitsance, 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 caposouls 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 base 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 week, and biochemical and body composition measurments 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

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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 resitsance, 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-alcohlic 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; takeing 400IU vitamin E daily. Exclusion criteria: Consumption of alcohol; Pregnancy or lactation and menopause; being athleteic; 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 antihypertensitives, 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
Begining 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 Indicies(TAC-ARE-MDA)
Timepoint
Beginning and end of the intervention
Method of measurement
TAC and ARE : spectrophotometry and MDA : thiobarbituric acid

7

Description
Sonography faindings
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 caposouls 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 weks 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
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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
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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