Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A Study on the Effect of Conjugated Lionleic Acid Supplementation on Body Composition, Blood Glucose, Serum Insulin, Serum Leptin and Lipid Profile in Obese Adults (18-45) of both genders

Protocol summary

Summary

This study has been designed aiming at study of the effect of CLA on the indices of weight, waist size, fat and lean body mass, serum level of Leptin and serum insulin, insulin resistance, level of gloucose and serum lipid patterns.This study will be conducted using the random clinical trial method of controlled double blind type with placebo on 60 obese adults of both genders (18-45) with a BMI given as 30-34.9 kg/m2. The individuals were chosen from among the clients referring to the Clinic of Nikan Hospital in the city of Tehran using randomizd parallel sampling method with a three months of intervention.the people will randomly received a daily amount of 3 g CLA (three 1000 mg capsules) or placebo (three 500 mg capsules containing paraffin oil).The study arrival criteria are given as follows: No weight loss or gain over 2 kg in the recent three months, the samples should have no record of diabetes, cardiac disorders, cerebral stroke, suffering from renal and hepatic diseases, chronic inflammatory diseases, thyroid diseases and gastroenterological diseases, not consuming hypoglycemic medicines, blood-pressure lowering drugs or anti blood presure medicines, beta blockers, steregene, porgesterone, not consuming any kinds of supplementations such as antioxidant vitamines, minerals, Omega 3 and CLA within two months prior to commencement of study, smoking, using alchoholic drinks, no respiratory or joint complications, not being pregnant or breastfeeding and having no intention for getting pregnant. Moreover, the samples suffering from specific complications such as epigasteric pains will be exclued from this study. The female samples will be excluded from this project in case of pregnancy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052413678N2**
Registration date: **2014-08-26, 1393/06/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-08-26, 1393/06/04

Registrant information

Name
Saeed Ghavamzadeh
Name of organization / entity
Urmia University of Medical Sciences
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Iran (Islamic Republic of)
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+98 44 1278 0803
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ghavamzadeh_s@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Urmia University Of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Study on the Effect of Conjugated Lionleic Acid Supplementation on Body Composition, Blood Glucose, Serum Insulin, Serum Leptin and Lipid Profile in Obese Adults (18-45) of both genders

Public title
A Study on the Effect of Conjugated Lionleic Acid Supplementation on Body Weight loss
Purpose
Treatment
Inclusion/Exclusion criteria
obese adults of both genders (18-45) with a BMI given as 30-34.9 kg/m2؛No weight loss or gain over 2 kg in the recent three months؛the samples should have no record of diabetes؛cariad disorders؛record of angina pectoris, myocardial infarction, cerebral stroke, suffering from renal and hepatic diseases؛ chronic inflammatory diseases؛ thyroid diseases and gastroenterological diseases؛ not consuming hypoglycemic medicines؛ blood-pressure lowering drugs or anti blood presure medicines؛ beta blockers؛ steregene؛ porgesterone؛ not consuming any kinds of supplementations such as antioxidant vitamines؛ minerals؛ Omega 3 and CLA within two months prior to commencement of study؛ smoking؛ using alchoholic drinks؛ no respiratory or joint complications؛ not being pregnant or breastfeeding and having no intention for getting pregnant. Moreover, the samples suffering from specific complications such as epigasteric pains will be exclued from this study؛ The female samples will be excluded from this project in case of pregnancy.
Age
From **75 years** old to **48 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Urmia University of Medical Sciences
Street address
Nutrition Department, Faculty of Medicine, College of Medicine, Urmia University of Medical Science, 11th km of Nazloo Road, Urmia
City
Urmia
Postal code
00984412780300
Approval date
2014-01-28, 1392/11/08
Ethics committee reference number
umsu.rec.1392.202

Health conditions studied

1

Description of health condition studied
Obesity
ICD-10 code
E66.9
ICD-10 code description
Obesity, unspecified

Primary outcomes

1

Description
Age
Timepoint
Before Intervention
Method of measurement
Life years from birth based on birth certificate card

2

Description
sex
Timepoint
Before Intervention
Method of measurement
with questionnaire

3

Description
weight
Timepoint
Before Intervention and three months after Intervention
Method of measurement
Kg/scale

4

Description
height
Timepoint
Before Intervention
Method of measurement

Meter/ribor meter

5

Description
BMI
Timepoint
Before Intervention and three months after Intervention
Method of measurement
Ratio of weight (kg) to height square (m)

6

Description
FM%
Timepoint
Before Intervention and three months after Intervention
Method of measurement
Percentage/Body Analyzer

7

Description
FFM%
Timepoint
Before Intervention and three months after Intervention
Method of measurement
Percentage/Body Analyzer

8

Description
FBS
Timepoint
Before Intervention and three months after Intervention
Method of measurement
Mg/dl/enzymatic method

9

Description
Cholesterol
Timepoint
Before Intervention and three months after Intervention
Method of measurement
Mg/dl/enzymatic method

10

Description
TG
Timepoint
Before Intervention and three months after Intervention
Method of measurement
Mg/dl/enzymatic method

11

Description
VLDL
Timepoint
Before Intervention and three months after Intervention
Method of measurement
Mg/dl/enzymatic method

12

Description
LDL
Timepoint
Before Intervention and three months after Intervention
Method of measurement
Mg/dl/enzymatic method

13

Description
HDL
Timepoint
Before Intervention and three months after Intervention
Method of measurement
Mg/dl/enzymatic method

14

Description
Leptin
Timepoint
Before Intervention and three months after Intervention
Method of measurement
Mg/dl /ELIZA

15

Description
Waist Size
Timepoint
Before Intervention and three months after Intervention
Method of measurement
Cm/ribbon meter

16

Description
Insulin Resistance
Timepoint
Before Intervention and three months after Intervention
Method of measurement
HOMA-IR (Homeostasis Model Assessment of Insulin Resistance) is the same resistance to insulin index which is calculated as follows. 405/(dl/mg) fasting glucose concentration* (ml/micro unit) active fasting insulin concentration

17

Description
Insulin
Timepoint
Before Intervention and three months after Intervention
Method of measurement
Micro unit per ml/ELIZA

18

Description
Carbohydrate Intake
Timepoint
Before Intervention and three months after Intervention

Method of measurement
gr/day

19

Description
Protein Intake
Timepoint
Before Intervention and three months after Intervention
Method of measurement
gr/day

20

Description
Fat Intake
Timepoint
Before Intervention and three months after Intervention
Method of measurement
gr/day

21

Description
Energy Intake
Timepoint
Before Intervention and three months after Intervention
Method of measurement
kcal/day

Secondary outcomes

1

Description
gastroenterological side effects
Timepoint
During Intervention
Method of measurement
Taking Report

Intervention groups

1

Description
After collecting the initial data,The case group will received daily amount of 3 g CLA (three 1000 mg soft gels) Three times a day Before main Meals for 3 Months.
Category
Placebo

2

Description
The control group will received a daily amount of1/5 gr placebo (three 500 mg soft gel containing paraffin oil)three times a day before main meals for three months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Nikan Hospital
Full name of responsible person
Fatemeh Esmaeili Shahmirzadi
Street address
Bistodoye Bahman, Ave Aghdasiyeh, Sq Tehran-Iran.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urmia University of Medical Science
Full name of responsible person
Dr. Saeed Ghavamzadeh
Street address
Nutrition Department, Faculty of Medicine, College of Medicine, Urmia University of Medical Science, 11th km of Nazloo Road, Urmia
City
Urmia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urmia University of Medical Science
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
Urmia University of Medical Sciences
Full name of responsible person
Dr. Saeed Ghavamzadeh
Position

Specialty Doctorte Degree inNutritioal Science AndUrmia University Assistant Professor

Other areas of specialty/work

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Full name of responsible person

Dr. Saeed Ghavamzadeh

Position

Specialty Doctorte Degree In Nurtitional Science/Urmia Universityof Medical Science Assistant Profes

Other areas of specialty/work

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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