Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of oleoylethanolamide supplementattion on the peroxisome proliferator-activated receptor-α (PPAR-α) gene expression, some inflammatory biomarkers, total antioxidant capacity, lipid profiles, fasting blood glucose, food intake and the abundence of Akkermansia muciniphila bacteria in stool of obese people: A double-blind randomized placebo-controlled clinical trial

Protocol summary

Study aim
The effect of Oleoylethanolamide supplementation on the total antioxidant capacity, lipid profiles, fasting blood glucose, and food intake in obese people

Design
randomized double blind clinical trial

Settings and conduct
educational centers and clinics of Tabriz university of medical scieces

Participants/Inclusion and exclusion criteria
inclusion criteria: ages between 18-59, BMI= 30-40 kg/m2 Exclusion criteria: kidney and liver diseases, heart failure, rheumatic diseases, gastrointestinal diseases, smoking, lactation , pregnancy, menopause, taking peobiotics and prebiotics supplement vitamins, omega 3 and weight losing drugs and antibiotics in the past one month

Intervention groups
The intervention group two 125 mg oleylethanolamide capsules daily Control group similar amounts of placebo (starch)

Main outcome variables
serum levels of total antioxidant capacity, fasting blood glucose, lipid profiles, dietary intake

General information

Reason for update

Acronym
Assessment of oleoylethanolamide supplementattion in the prevention and treatment of obesity

IRCT registration information
IRCT registration number: **IRCT201607132017N30**
Registration date: **2016-10-03, 1395/07/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-30, 1398/06/08**
Update count: **1**

Registration date
2016-10-03, 1395/07/12

Registrant information

Name
Alireza Ostadrahimi

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice-chancellor for Research of Tabriz University of Medical Sciences

Expected recruitment start date
2016-09-22, 1395/07/01

Expected recruitment end date
2018-04-21, 1397/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Assessment of oleoylethanolamide supplementattion on the peroxisome proliferator-activated receptor-α (PPAR-α) gene expression, some inflammatory biomarkers, total antioxidant capacity, lipid profiles, fasting blood glucose, food intake and the abundence of Akkermansia muciniphila bacteria in stool of obese people: A double-blind randomized placebo-controlled clinical trial

Public title
Assessment of oleoylethanolamide supplementattion in the prevention and treatment of obesity
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
healthy obese subjects in both genders (males and females) Ages between 18 to 59 years body mass index 30-40 kg/m2
Exclusion criteria:
having kidney problems, liver failure, heart failure, rheumatic diseases and gastrointestinal diseases smoking Breastfeeding and pregnancy and menopause Taking probiotic and prebiotic supplements, vitamin, minerals, omega-3 and weight-reducing drugs and antibiotics during past one month
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals with inclusion criteria divided into intervention and control groups using Random allocation software (RAS)
Blinding (investigator's opinion)
Double blinded
Blinding description
The intervention and control groups individuals which use oleoylethanolamide and placebo (starch), respectively and main researcher will be blinded in terms of the types of supplements
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
Street address
Faculty of Nutrition and Food sciences, Tabriz University of Medical Sciences Attar Neishabouri Street. Gholgasht street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
041-33357584
Approval date
2016-09-07, 1395/06/17
Ethics committee reference number
IR.TB MED.REC.1395.618

Health conditions studied

1

Description of health condition studied
obesity
ICD-10 code
E66.0
ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
gene expression of PPAR-α
Timepoint
before and after supplementation
Method of measurement
Real time-PCR

2

Description
inflammatory biomarkers (IL-6، TNF-α ، hs-CRP)
Timepoint
before and after supplemenation
Method of measurement
IL-6 and TNF-α using ELISA, hs-CRP using spectrometry method

3

Description
The abundance of Akkermansia muciniphila bacteria in stool samples
Timepoint
before and after supplemenation

Method of measurement
colony count

4

Description
total antioxidant capacity
Timepoint
before and after supplemenation
Method of measurement
using ELISA method

5

Description
lipid profiles and fasting blood glucose
Timepoint
before and after supplementation
Method of measurement
Using ELISA method

6

Description
Dietary intake
Timepoint
before and after supplemenation
Method of measurement
Three days food record questionnaire

Secondary outcomes

1

Description
Anthropometric measurements
Timepoint
at baseline and at the end of intervention
Method of measurement
Using a stadiometertape and tape in accordance with the standards

2

Description
appetite status
Timepoint
at baseline and at the end of study
Method of measurement
Visual Analouge Scale questionnaire

Intervention groups

1

Description
intervention group: daily 2 capsules including 125 mg oleoylethanolamide for eight weeks
Category
Prevention

2

Description
control group: daily 2 capsule including 125 mg starch for eight weeks
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Sheikhoilraies Clinic of Tabriz University of Medical Science
Full name of responsible person
Alireza Ostadrahimi
Street address
Attar Neyshaburi Street, Golgasht Avenue , Nutrition faculty, Tabriz University of Medical Science, Ground Floor
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor for Research of Tabriz University of Medical Sciences
Full name of responsible person
Dr Alireza Ostadrahimi
Street address
Third floor, Central Building (2), Tabriz University of Medical Scienes, Golgasht Avenue
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ostadrahimi@tbzmed.ac.ir
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 of Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Nutrition, Tabriz University of Medical Science

Full name of responsible person

Laleh Payahoo

Position

pH.D

Latest degree

Ph.D.

Other areas of specialty/work

Street address

Nutrition Faculty, Attar Neyshaburi Street, Golgasht Avenue

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Alireza Ostadrahimi

Position

Assistance professor

Latest degree

Subspecialist

Other areas of specialty/work

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Laleh Payahoo

Position

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Latest degree

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Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there is not more data

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable