

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 abundance 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

Country

Iran (Islamic Republic of)

Phone

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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 abundance 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

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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 supplementation

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 supplementation

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 Analogue 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

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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

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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**

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Full name of responsible person

Laleh Payahoo

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Web page address**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

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Nutrition Faculty, Tabriz University of Medical Sciences

Full name of responsible person

Dr Alireza Ostadrahimi

Position

Assistance professor

Latest degree

Subspecialist

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