Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessment of oleoylethanolamide supplementation on the expression of SIRT1, AMPK, PGC-1α, PPAR-γ, CEBP-α, CEBP- β, IL-6, and IL-10 genes, serum IL-6, IL-10, hs-CRP, IL-1β, TNF-α, TAC, GSH-Px, SOD, catalase, MDA, ox-LDL, and NRG-4 levels, and body composition in obese patients with non-alcoholic fatty liver disease (NAFLD)

Protocol summary

Study aim

This double-blind randomized placebo-controlled clinical trial will be done with the aim of oleoylethanolamide (OEA) supplementation on the SIRT1, AMPK, PGC1-α, PPAR-γ, CEBP-α, CEBP-β, IL-6, and IL-10 genes expression, and serum levels of IL-6, IL-10, hs-CRP, IL-1β, TNF-α, TAC, GSH-Px, SOD, catalase, MDA, ox-LDL, and NRG-4, and body composition in obese patients with non-alcoholic fatty liver disease (NAFLD).

Design

This study will be done on sixty obese patients of both genders with NAFLD.

Settings and conduct

The study will be conducted in the nutrition faculty of Tabriz University of Medical Sciences and supplementation duration will be 12 weeks. The OEA and placebo sachets will be coded by the person responsible for preparing them, and the main investigators and the patients will be blinded to the type of the supplement each group receives.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Body mass index 30 to 40 kg/m2, and non-alcoholic fatty liver disease Exclusion criteria: Use of drugs and supplements. smoking, pregnancy, breastfeeding, menopause, liver, kidney and gastrointestinal diseases, diabetes, heart failure, thyroid disorders

Intervention groups

patients in the OEA group will use two125 mg OEA capsules daily. In the placebo group, two 125 mg capsules of starch will be consumed daily.

Main outcome variables

The body composition percentage The expression of SIRT1, AMPK, PGC-1α, PPAR-γ, CEBP-α, CEBP-β, IL-6, and IL-10 genes serum levels of IL-6. IL-10, hs-CRP, IL-1β, TNF-α, TAC, GSH-Px, SOD, catalase, MDA, ox-LDL, and NRG-4

General information

Reason for update

To add the effects of oleoylethanolamide (OEA) supplementation on the serum levels of hs-CRP, IL-1β, TNF-α, TAC, GSH-Px, SOD, catalase, MDA, and ox-LDL

Acronym

IRCT registration information

IRCT registration number: **IRCT20090609002017N32**
Registration date: **2018-08-11, 1397/05/20**
Registration timing: **prospective**

Last update: **2022-09-06, 1401/06/15**
Update count: **2**

Registration date

2018-08-11, 1397/05/20

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

Expected recruitment start date
2019-04-21, 1398/02/01
Expected recruitment end date
2020-01-21, 1398/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of oleoylethanolamide supplementation on the expression of SIRT1, AMPK, PGC-1α, PPAR-γ, CEBP-α, CEBP- β, IL-6, and IL-10 genes, serum IL-6, IL-10, hs-CRP, IL-1β, TNF-α, TAC, GSH-Px, SOD, catalase, MDA, ox-LDL, and NRG-4 levels, and body composition in obese patients with non-alcoholic fatty liver disease (NAFLD)

Public title
Assessment of Oleoylethanolamide supplementation in prevention and treatment of non-alcoholic fatty liver disease
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Ages between 20 to 50 years body mass index (BMI) 30 to 40 kg/m2 Diagnosis of non-alcoholic fatty liver disease by a liver specialist based on ultrasound
Exclusion criteria:
Regular use of nonsteroidal anti-inflammatory agents (NSAIDs) and antibiotics Use of hepatotoxic drugs such as phenytoin, amiodarone, levothyroxine, amoxifene, lithium Use of antihypertensive drugs Using weight loss and lipid-lowering drugs Use of probiotic and prebiotic supplements; vitamins; minerals; antioxidants; and omega 3 supplements in the last 3 months Smoking Pregnancy Breast-feeding Menopause Pathological conditions affecting the liver such as viral hepatitis, acute or chronic hepatic impairment, liver transplantation, acute systemic disease Gastrointestinal diseases Diabetes Heart failure Thyroid disorders Kidney Diseases Haemochromatosis Wilson's disease Alpha-1 antitrypsin deficiency Autoimmune diseases
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples are assigned to intervention and control groups using simple random design
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the main investigator and patients will be blind (oleoylethanolamide or placebo) .
The person responsible for preparing the supplement sac hets
(who is completely unrelated to the study) will be asked to assign a three
digit code to each of the two powders (oleoylethanolamid and placebo), and keep the codes for himself until the en d of the study and data analyses.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Tabriz University of Medical Sciences
Street address
Third Floor, Central Building (2), Tabriz University of Medical Sciences, Golghasht Street
City
Tabriz
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00984133344280
Approval date
2018-05-21, 1397/02/31
Ethics committee reference number
IR.TBZMED.REC.1397.176

2

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Approval date
2020-12-28, 1399/10/08

Ethics committee reference number
IR.TBZMED.REC.1399.908

3

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Approval date
2022-07-31, 1401/05/09
Ethics committee reference number
IR.TBZMED.REC.1401.425

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
gene expression of IL-6
Timepoint
before intervention, and 3 months after intervention
Method of measurement
Real time-PCR

2

Description
gene expression of IL-10
Timepoint
before intervention, and 3 months after intervention
Method of measurement
Real time- PCR

3

Description
Serum levels of IL-6
Timepoint
before intervention, and 3 months after intervention
Method of measurement
By laboratory ELISA kits

4

Description
Serum levels of IL-10
Timepoint
Before intervention, and 3months after intervention
Method of measurement
By laboratory ELISA kits

5

Description
Serum levels of NRG-4
Timepoint
Before intervention, and 3months after intervention
Method of measurement
By laboratory ELISA kits

6

Description
gene expression of SIRT1
Timepoint
before intervention, and 3 months after intervention
Method of measurement
Real time-PCR

7

Description
gene expression of AMPK
Timepoint
before intervention, and 3 months after intervention
Method of measurement
Real time-PCR

8

Description
gene expression of PGC-1α
Timepoint
before intervention, and 3 months after intervention
Method of measurement
Real time-PCR

9

Description
gene expression of PPAR-γ
Timepoint
before intervention, and 3 months after intervention
Method of measurement
Real time-PCR

10

Description
gene expression of CEBP-α
Timepoint
before intervention, and 3 months after intervention
Method of measurement
Real time-PCR

11

Description
gene expression of CEBP-β
Timepoint
before intervention, and 3 months after intervention
Method of measurement
Real time-PCR

12

Description
Serum levels of hs-CRP
Timepoint
before intervention, and 3 months after intervention
Method of measurement
By laboratory ELISA kits

13

Description
Serum levels of IL-1β
Timepoint
before intervention, and 3 months after intervention
Method of measurement
By laboratory ELISA kits

14

Description
Serum levels of TNF-α
Timepoint
before intervention, and 3 months after intervention
Method of measurement
By laboratory ELISA kits

15

Description
Levels of total antioxidant capacity (TAC)
Timepoint
before intervention, and 3 months after intervention
Method of measurement
By colorimetric method using Randox total antioxidant status kit

16

Description
Levels of glutathione peroxidase (GSH-Px)
Timepoint
before intervention, and 3 months after intervention
Method of measurement
By spectrophotometric method using Ransel and Ransod kits

17

Description
Levels of superoxide dismutase (SOD)
Timepoint
before intervention, and 3 months after intervention
Method of measurement
By spectrophotometric method using Ransel and Ransod kits

18

Description
Level of malondialdehyde (MDA)
Timepoint
before intervention, and 3 months after intervention
Method of measurement
By the spectrophotometric thiobarbituric acid reactive substances (TBARS) method

19

Description
Levels of catalase activity
Timepoint
before intervention, and 3 months after intervention
Method of measurement
By Aebi's method

20

Description
Serum levels of oxidized-low density lipoprotein (ox-LDL)
Timepoint
before intervention, and 3 months after intervention
Method of measurement
By laboratory ELISA kits

Secondary outcomes

1

Description
Body composition
Timepoint
Before intervention, and 3 months after intervention
Method of measurement
Measurement of body composition, including fat mass, fat free mass and total body water determination using bioelectrical impedance analyser (BIA)

Intervention groups

1

Description
Intervention group: daily 2 capsules including 125 mg oleoylethanolamide
Category
Prevention

2

Description
Control group: daily 2 capsules including 125 mg placebo
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Health centers of Tabriz University of Medical Sciences

Full name of responsible person
Alireza Ostadrahimi

Street address
Attar Neyshabouri 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 , Tabriz University of Medical Sciences, Nutrition Research Center

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 , Tabriz University of Medical Sciences, Nutrition Research Center

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
Nutrition Faculty, Tabriz University of Medical Sciences

Full name of responsible person
Helda Tutunchi

Position
Ph.D Candidate

Latest degree
Master

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

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

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

Title and more details about the data/document
Data collected for the primary outcomes will be shared.

When the data will become available and for how long
access starting 12 months after publication

To whom data/document is available
The data will only be available for people working in acad emic institutions.

Under which criteria data/document could be used
The data of the present study will only be accessible by o ther researchers, for conducting Meta-analysis.

From where data/document is obtainable
The researchers (student and her supervisor)

What processes are involved for a request to access data/document
Request a document via email

Comments