Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

The effect of Oleoylethanolamide supplementation on peroxisome proliferator-activated receptor alpha gene expression, pyroptosis pathway genes (TLR4, TRIF, MYD88, NLRP3, Caspase 1, Caspase 8, IL1β and IL18), lipopolysaccharide binding protein, metabolic parameters, and anthropometric indices in obese patients with non-alcoholic fatty liver disease

Protocol summary

Study aim

The aim of the present study is to investigate the effects of Oleoylethanolamide supplementation on peroxisome proliferator-activated receptor alpha gene expression, pyroptosis pathway genes (TLR4, TRIF, MYD88, NLRP3, Caspase 1, Caspase 8, IL1β and IL18), lipopolysaccharide binding protein, metabolic parameters, and anthropometric indices in peripheral blood mononuclear cells in obese NAFLD patients.

Design

Randomized triple-blinded controlled clinical trial with two arm parallel groups

Settings and conduct

The study will be conducted in School of Nutrition and Food Sciences of Tabriz University of Medical Sciences and duration of intervention will be 12 weeks. The Oleoylethanolamide and placebo capsules will be prepared and coded by the person responsible, and the main investigator and the patients will be blinded to the type of the supplement for each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20 to 50 years old, body mass index of 30 to 40 kg/m2 and non-alcoholic fatty liver disease based on ultrasonography - Exclusion criteria: Use of drugs and supplements, pregnancy, breastfeeding, liver, kidney and gastrointestinal diseases, diabetes, heart failure and thyroid disorders

Intervention groups

Patients in the Oleoylethanolamide (OEA) group will take two 125 mg OEA capsules daily. In the placebo group, two 125 mg starch capsules will be consumed daily.

Main outcome variables

The expression of the peroxisome proliferator-activated receptor alpha gene expression, pyroptosis pathway genes (TLR4, TRIF, MYD88, NLRP3, Caspase 1, Caspase 8, IL1β, and IL18), lipopolysaccharide binding protein, metabolic parameters, anthropometric indices, serum levels of alanine transaminase (ALT) and aspartate transfusion aminease (AST), the severity of liver steatosis, liver fibrosis score, dietary pattern and appetite sensations

General information

Reason for update

Adding information of two further studies related to this project

Acronym

IRCT registration information

IRCT registration number: **IRCT20110530006652N2**
Registration date: **2019-02-07, 1397/11/18**
Registration timing: **prospective**

Last update: **2020-05-09, 1399/02/20**
Update count: **1**

Registration date

2019-02-07, 1397/11/18

Registrant information

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-04-09, 1398/01/20
Expected recruitment end date
2020-03-05, 1398/12/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Oleoylethanolamide supplementation on peroxisome proliferator-activated receptor alpha gene expression, pyroptosis pathway genes (TLR4, TRIF, MYD88, NLRP3, Caspase 1, Caspase 8, IL1β and IL18), lipopolysaccharide binding protein, metabolic parameters, and anthropometric indices in obese patients with non-alcoholic fatty liver disease

Public title
Evaluation of Oleoylethanolamide supplementation in the prevention and treatment of non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 to 50 years old Body mass index (BMI) of 30 to 40 Kg/m2 Diagnosis of non-alcoholic fatty liver disease by a radiologist based on ultrasonography
Exclusion criteria:
Regular use of non-steroidal anti-inflammatory drugs (NSAIDs), antibiotics and corticosteroids Use of hormonal drugs, hepatotoxic drugs (such as Phenytoin, Amiodarone, Levothyroxine, Tamoxifene and Lithium), anti-hypertensive drugs, weight loss and lipid lowering drugs Use of prebiotic and probiotic supplements, vitamins, minerals, antioxidants, and omega 3 supplements Diagnosed pathological conditions affecting the liver such as liver transplantation, acute or chronic hepatic impairment, viral hepatitis, cystic fibrosis, Haemochromatosis, Wilson's disease, Alpha-1 antitrypsin deficiency, and acute systemic disease Diagnosed thyroid disorders Diagnosed kidney diseases Diagnosed gastrointestinal diseases (e.g. Celiac disease) Diagnosed diabetes Diagnosed heart failure Diagnosed autoimmune diseases Diagnosed malignancies Diagnosed severe psychological disorders Pregnancy and lactation
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Among volunteers to participate in the study, 74 individuals will be selected by simple randomization. Then the subjects will be allocated into either intervention or placebo group by the Random Allocation Software, based on their gender and grade of fatty liver.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, the main investigator, the patients and the data analyst will be blinded to the supplement type (Oleoylethanolamide or placebo).
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
Tabriz University of Medical Sciences, Golghasht Street
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Tabriz
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5166614711
Approval date
2018-11-19, 1397/08/28
Ethics committee reference number
IR.TBZMED.REC.1397.694

2

Ethics committee
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Approval date
2020-01-21, 1398/11/01
Ethics committee reference number
IR.TBZMED.REC.1398.1131

3

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Approval date
2020-02-04, 1398/11/15
Ethics committee reference number
IR.TBZMED.REC.1398.1175

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 PPAR-α
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Real time-PCR

2

Description
Serum levels of triglyceride
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
enzymatic kit

3

Description
Serum levels of total cholesterol
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
enzymatic kit

4

Description
Serum levels of High-Density Lipoprotein cholesterol (HDL-c)
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
enzymatic kit

5

Description
Serum levels of Low-Density Lipoprotein cholesterol (LDL-c)
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
enzymatic kit

6

Description
Fasting blood glucose levels
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
enzymatic kit

7

Description
Fasting insulin levels
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

8

Description
Gene expression of TLR4
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Real-time PCR

9

Description
Gene expression of NLRP3
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Real-time PCR

10

Description
Gene expression of Caspase1
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Real-time PCR

11

Description
Gene expression of IL18
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Real-time PCR

12

Description
serum level of LBP
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

13

Description
Gene expression of MYD88
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Real-time PCR

14

Description
Gene expression of TRIF
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Real-time PCR

15

Description
Gene expression of Caspase 8
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Real-time PCR

16

Description
Gene expression of IL1- β
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Real-time PCR

Secondary outcomes

1

Description
Serum levels of alanine transaminase (ALT)
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
enzymatic kit

2

Description
Serum levels of aspartate aminotransferase (AST)
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
enzymatic kit

3

Description
Severity of liver steatosis
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Ultrasonography

4

Description
Liver fibrosis score
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Non-alcoholic fatty liver disease (NAFLD) fibrosis score formula

5

Description
Dietary assessment

Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Dietary recall

6

Description
Appetite assessment
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Visual analog scales (VAS)

7

Description
Anthropometric incidies
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Waist circumference by a non-stretching measuring tape - BMI by dividing weight (kg) to height square (m2) - WHR by waist circumference/hip circumference

8

Description
Physical activity
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
The International Physical Activity Questionnaires (IPAQ)

Intervention groups

1

Description
Intervention group: Patients in this group will receive a weight-loss diet (500 Kcal less than current intake) and Oleylethanolamide supplements (125 mg) for 12 weeks. The Oleylethanolamide supplements are made in Islamic Republic of Iran and will be consumed twice (before lunch and dinner) daily .
Category
Treatment - Drugs

2

Description
Control group: Patients in this group will receive a weight-loss diet (500 Kcal less than current intake) with placebo for 12 weeks. The placebo is starch (125 mg) and will be consumed twice daily before lunch and dinner.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers of Tabriz University of Medical Sciences
Full name of responsible person
Dr. Maryam Saghafi-Asl
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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Research Vice-chancellor, Attar Neishabouri Street, Golgasht Avenue
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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
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
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Full name of responsible person
Helda Tutunchi
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Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be 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
Publication of Results
When the data will become available and for how long
After finishing and publishing the project article
To whom data/document is available
University researchers
Under which criteria data/document could be used
With permission from the project researcher and the supporting organization (Nutrition Research Center and the Deputy of Research)
From where data/document is obtainable
Dr. Maryam Saghafi-Asl - School of Nutrition and Food Sciences, Tabriz University of Medical Sciences - Email: Saghafiaslm@gmail.com
What processes are involved for a request to access data/document
The recipient can send a request to the study corresponding person via email
Comments