

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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, IL1 β 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, IL1 β 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, IL1 β , and IL18), lipopolysaccharide binding protein, metabolic parameters, anthropometric indices, serum levels of alanine transaminase (ALT) and aspartate transaminase (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

Name

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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, IL1 β 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

City

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Postal code

5166614711

Approval date

2018-11-19, 1397/08/28

Ethics committee reference number

IR.TBZMED.REC.1397.694

2

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

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Approval date

2020-01-21, 1398/11/01

Ethics committee reference number

IR.TBZMED.REC.1398.1131

3**Ethics committee****Name of ethics committee**

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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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School of Nutrition and Food Sciences, Golgasht Street

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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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Samiei.moh@gmail.com

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****Name of organization / entity**

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 scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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

