

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Aug 2026

The Effect of Oleoylethanolamide on Glycemic control, Serum Levels of TNF- α and miRNA126a in Patients with Type 2 Diabetes

Protocol summary

Study aim

The Effect of Oleoylethanolamide on Glycemic Control, Serum Levels of TNF- α and miRNA126a in Patients with Type 2 Diabetes

Design

A study will involve 66 patients with type 2 diabetes, divided into two groups: one receiving 200 mg of OEA supplement and the other a placebo for 3 months. Participants will also follow a restricted-calorie diet and increased physical activity. Adherence to the interventions will be monitored through weekly contacts and pill counts.

Settings and conduct

This study will be conducted at the Research Institute of Endocrinology and Metabolism at the Tehran University of Medical Sciences. Blood samples will be collected from participants before and after the intervention to assess serum levels of TNF- α , HbA1c, and GLP-1 using ELISA, and miRNA-146-a using Real-Time PCR. Blood glucose levels will be measured with an auto-analyzer. Food intake and anthropometric indices will be measured at the beginning and end of the study as well.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with type 2 diabetes, aged 18-65 years, willing to participate in the study, having body mass index (BMI) > 25 kg/m² Exclusion criteria: Patients with any metabolic disease and a history of drug or alcohol abuse within the past 6 months

Intervention groups

Diabetes patients who receive 200 mg of OEA supplement

Main outcome variables

FPG, Insulin, HbA1c, GLP-1, TNF- α , miRNA 146a, age, sex, weight, Waist/hip circumference, Body mass index, Food intake

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240924063143N1**

Registration date: **2024-12-11, 1403/09/21**

Registration timing: **prospective**

Last update: **2024-12-11, 1403/09/21**

Update count: **0**

Registration date

2024-12-11, 1403/09/21

Registrant information

Name

Pooneh pazhoohandeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6652 2791

Email address

jafari.r@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-21, 1403/10/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Oleoylethanolamide on Glycemic control, Serum Levels of TNF- α and miRNA126a in Patients with Type 2 Diabetes

Public title

The effect of oral Oleoylethanolamide supplement on glycemic control and inflammation in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with type 2 diabetes, age 18-65 years, body mass index 40-25, no change in oral medications and lifestyle in the last 3 months, consent to participate in the research and follow its processes

Exclusion criteria:

Patients with a history of hypertension hyperparathyroidism, malignancy, renal or hepatic failure, drug or alcohol abuse within the past 6 months, allergy or intolerance to any kind of dietary supplements, Pregnant and lactating women Using GLP-1 agonists or DDP-4 inhibitors Any changes in the type or dosage of medications during the study Non-adherence to the trial is defined as refusing to consume at least 10% of recommended treatments

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **66**

More than 1 sample in each individual

Number of samples in each individual: **2**

One sample before the intervention and one sample after the intervention

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: The online "Sealed envelope" software will perform randomization based on gender and BMI using the block randomization method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The diabetes clinic specialist will enter the participants into different groups using consecutive codes and explain the treatments to the participants and check their adherence. All researchers, participants, and data analysts will be blind to treatment.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tehran University of Medical Sciences

Street address

Boulevard Keshavarz, Corner of Quds, Tehran University of Medical Sciences.

City

Tehran

Province

Tehran

Postal code

1411713119

Approval date

2024-09-24, 1403/07/03

Ethics committee reference number

IR.TUMS>EMRI>REC.1403.081

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

E11.8

ICD-10 code description

Type 2 diabetes mellitus with unspecified complications

Primary outcomes

1

Description

Oleoylethanolamide (OEA) supplement

Timepoint

Before the intervention

Method of measurement

A supplement which provided to participants in 200 mg capsules.

2

Description

Age

Timepoint

Before the intervention

Method of measurement

Years of life with identification document observation.

3

Description

Gender.

Timepoint

Before the intervention

Method of measurement

Female or male phenotypic appearance

4**Description**

Weight

Timepoint

Before the intervention

Method of measurement

The body mass of an individual, expressed in pounds or kilograms, is measured using a scale.

5**Description**

Waist circumference

Timepoint

Before the intervention

Method of measurement

Waist circumference will be measured using a measuring tape.

6**Description**

Hip circumference

Timepoint

Before the intervention

Method of measurement

Measuring the hip circumference using a tape measure.

7**Description**

Body mass index (BMI).

Timepoint

Before the intervention

Method of measurement

This index is obtained by dividing weight in kilograms by the square of height in meters and is used to assess the degree of overweight and obesity.

8**Description**

Food intake

Timepoint

Over a period of 3 months

Method of measurement

The quantity and type of food items recorded by the individual over three days (two regular days and one holiday) are analyzed using software.

9**Description**

Fasting blood glucose

Timepoint

Before and after the intervention

Method of measurement

Glucose oxidase laboratory kit

10**Description**

TNF- α (Tumor Necrosis Factor Alpha)

Timepoint

Before and after the intervention

Method of measurement

Immunoassay (ELISA test (Enzyme-Linked Immunosorbent Assay))

11**Description**

MicroRNA (miRNA) 126a

Timepoint

Before and after the intervention

Method of measurement

Real-time polymerase chain reaction (Real -time PCR)

12**Description**

Homeostasis Model Assessment of Insulin Resistance

Timepoint

Before and after the intervention

Method of measurement

Will be calculated using formula

13**Description**

Homeostasis Model Assessment of Beta-cell function (HOMA-B)

Timepoint

Before and after the intervention

Method of measurement

Will be calculated using formula

14**Description**

Hemoglobin a1c

Timepoint

Before and after the intervention

Method of measurement

Immunoassay (Eenzyme linked immunosorbent assay)

15**Description**

Glycemic index

Timepoint

Before and after the intervention

Method of measurement

Will be calculated using formula

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: including 33 participant receiving 200 mg of OEA supplement per day

Category

Treatment - Drugs

2

Description

Control group: including 33 people receiving 200 mg capsules of the same size and color containing cellulose

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences

Full name of responsible person

Pooneh Pazhoohandeh

Street address

Jalal Al Ahmad Highway - Next to Shariati Hospital

City

Tehran

Province

Tehran

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1411713119

Phone

+98 21 8863 1297

Email

emrc@tums.ac.ir

Web page address

<https://emri.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hoda Derakhshanian

Street address

No 3, Hojjat Doost Street, Naderi Street, Keshavarz Boulevard, Tehran, Iran

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Info_snsd@tums.ac.ir

Web page address

<https://snsd.tums.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Hoda Derakhshanian

Position

Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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No 32, Hojjat Doost Street, Naderi Street, Keshavarz Boulevard, Tehran, Iran

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h.derakhshanian@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hoda Derakhshanian

Position

Faculty Member

Latest degree

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Other areas of specialty/work

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

Tehran University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Email

h.derakhsanian@gmail.com

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data from this study will be provided confidentially to upstream policymakers upon request. Additionally, the methodology of the clinical study, the results of this study, and the statistical analyses will be published in the form of an article and made available to the public.

When the data will become available and for how long

2024

To whom data/document is available

Policymakers and Researchers

Under which criteria data/document could be used

Conducting supplementary studies or writing review articles.

From where data/document is obtainable

Tehran University of Medical Sciences - School of
Nutrition Sciences - Boulevard Kashavarz, Naderi Street,
Hojat Doost Street, No. 44 - Dr. Hedi Derakhshanian.
h.derakhsanian@gmail.com

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

Requests for data usage can be submitted via email or in person at the following address: Tehran University of Medical Sciences - School of Nutrition Sciences - Boulevard Kashavarz, Naderi Street, Hojat Doost Street, No. 44 - Dr. Hoda Derakhshanian.

Comments