Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 patientswith 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
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Tehran
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1411713119
Phone
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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
Street address
No 32, Hojjat Doost Street, Naderi Street, Keshavarz Boulevard, Tehran, Iran
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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
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