Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Evaluation of the effect of oral oleoylethanolamide (OEA) supplement on glycemic indexes, insulin resistance and C-reactive protein in pre-diabetic patients: A double-blind controlled clinical trial with placebo

Protocol summary

Study aim

Determining the effect of Oleoylethanolamide oral supplementation on the glycemic index, insulin resistance, and C-reactive protein in pre-diabetic patients

Design

In this study, 44 patients with prediabetes who are eligible for inclusion in the study and referred to the Department of Endocrinology and Metabolism of Velayat Hospital of Qazvin University of Medical Sciences are selected. Participants are randomly assigned to two intervention and control groups and each participant is assigned a code.

Settings and conduct

This study will be done by referring to the Specialty Hospital of Qazvin University of Medical Sciences. The intervention and control group will receive 125 mg of Oleoylethanolamide or placebo daily for 2 months, respectively. Each person will complete questionnaires of individual consent, physical activity, and 24-hour recall. Fasting blood samples were also collected at the beginning and end of the study in 10 ml from participants. In this study, participants will be randomly divided into two groups (22 persons) through the table of random numbers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to work, prediabetes, age 25- 55, non-modification of treatment and medications for at least the past 2 months, moderate physical activity Exclusion criteria: Pregnancy and lactation, patients with severe renal and hepatic dysfunction, alcohol consumption

Intervention groups

Intervention group: the group receiving Oleoylethanolamide (125 mg daily) Control group: placebo group

Main outcome variables

Fasting blood sugar, 2 hours sugar, Glycosylated hemoglobin, insulin resistance, an inflammatory factor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141025019669N16**
Registration date: **2021-03-10, 1399/12/20**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-10, 1399/12/20**
Update count: **0**

Registration date

2021-03-10, 1399/12/20

Registrant information

Name

Hossein Khadem Haghighian

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-27, 1399/12/09

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of oral oleoylethanolamide (OEA) supplement on glycemic indexes, insulin resistance and C-reactive protein in pre-diabetic patients: A double-blind controlled clinical trial with placebo

Public title
Oleoylethanolamide supplementation effect in patients with prediabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men and women with prediabetes Willingness to work Age 25- 55 Non-modification of treatment and medications for at least the past 2 months Moderate physical activity
Exclusion criteria:
Pregnancy and breastfeeding Patients with severe renal and hepatic dysfunction Alcohol consumption
Age
From **24 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be allocated to trial groups (intervention and placebo groups) randomly using Random Allocation Software (RAS) through random block sizes of 4 and 6 with an allocation ratio of 1:1. Patients will receive a sealed container of supplements. Random sequencing allocation will be produced by the person who has not participate in the research. Containers will be numbered from 1 to 44 according to the sequence generated.
Blinding (investigator's opinion)
Double blinded
Blinding description
Supplements and placebo will be placed in similar containers and encode by someone except the investigator, so patients and the investigator will be blinded to medicine and placebo groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University Of Medical Sciences
Street address
Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin
City
Qazvin
Province
Qazvin
Postal code
34197-59811
Approval date
2021-02-22, 1399/12/04
Ethics committee reference number
IR.QUMS.REC.1399.482

Health conditions studied

1

Description of health condition studied
Prediabetes
ICD-10 code
R73.02
ICD-10 code description
Impaired glucose tolerance (oral)

Primary outcomes

1

Description
Fasting blood sugar
Timepoint
Before the intervention and after the intervention
Method of measurement
Eliza

2

Description
2 hours sugar
Timepoint
Before the intervention and after the intervention
Method of measurement
Eliza

3

Description
Insulin resistance
Timepoint

Before the intervention and after the intervention

Method of measurement

Using the formula

4

Description

Glycosylated hemoglobin

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

5

Description

Inflammatory factor

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Oleoylethanolamide, a capsule 125 mg per daily for two months, Manufacturer: Supplement Spot

Category

Treatment - Drugs

2

Description

Control group: A daily placebo capsule containing wheat flour for two months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Hossein Khadem Haghighian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Emam Jome

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Hossein Khadem Haghighian

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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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
All data after people are unrecognizable
When the data will become available and for how long
After completing the study and analyzing the data
To whom data/document is available
All researchers
Under which criteria data/document could be used
There is no objection to the use of data provided the source of the resource.
From where data/document is obtainable
By contacting the email address of a person responsible for general inquiries khademnut@yahoo.com
What processes are involved for a request to access data/document
Six months after the study
Comments