

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Aug 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)

Phone

+98 28 3375 2135

Email address

khadem.h@ajums.ac.ir

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

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

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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 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

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