

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Aug 2026

Survey the effect of oleoylethanolamide on fasting blood sugar level, insulin resistance, lipid profile, oxidative stress status, inflammatory factors, sex hormones levels and anti-Müllerian hormone in women with poly cystic ovarian syndrome

Protocol summary

Study aim

Determination of oleoylethanolamide supplement effect in women with poly cystic ovarian syndrome

Design

In this study, 80 patients with the poly cystic ovarian syndrome who are eligible to enter the study are selected. Participants are randomly divided into intervention and control groups and each participant will be assigned a code.

Settings and conduct

The aim of this study is to evaluate the oleoylethanolamide supplement as a randomized, double-blind clinical trial on patients with poly cystic ovary syndrome referring to the specialized department of the hospital of Qazvin University of Medical Sciences. People with poly cystic ovarian syndrome after the introduction by a gynecologist, counselor for this project, will be randomly divided into two groups of intervention and control.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the patients who are 18-45 years old diagnosed with the polycystic ovarian syndrome; having at least two criteria from Rotterdam's three criteria to diagnose this syndrome; BMI of less than 30; signed consent by the patient. Exclusion criteria: pregnancy; lactation; menopause; infectious disease; inflammatory disease; Cushing's syndrome; adrenal gland tumor; hypothyroidism; increased prolactinemia; acromegaly; diabetes and cancer; hormone therapy over the past three months; taking antioxidant supplements over the past three months, drug use over the past three months includes contraceptives; glucocorticoids; lipid-lowering drugs and weight loss drugs.

Intervention groups

Intervention group: the group receiving oleoylethanolamide (125 mg daily). Control group:

placebo group.

Main outcome variables

Fasting blood sugar; insulin resistance; lipid profile; oxidative stress indices; inflammatory factors; sex hormones; Anti-Müllerian hormone and sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141025019669N20**

Registration date: **2022-01-09, 1400/10/19**

Registration timing: **prospective**

Last update: **2022-01-09, 1400/10/19**

Update count: **0**

Registration date

2022-01-09, 1400/10/19

Registrant information

Name

Hossein Khadem Haghighian

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 28 3375 2135

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-15, 1400/10/25
Expected recruitment end date
2022-04-19, 1401/01/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Survey the effect of oleoylethanolamide on fasting blood sugar level, insulin resistance, lipid profile, oxidative stress status, inflammatory factors, sex hormones levels and anti-Mullerian hormone in women with poly cystic ovarian syndrome

Public title
Oleoylethanolamide supplementation in women with the poly cystic ovarian syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patients who are 18-45 years old diagnosed with the poly cystic ovarian syndrome Having at least two criteria from Rotterdam's three criteria to diagnose this syndrome; BMI of less than 30 Signed consent by the patient

Exclusion criteria:

Pregnancy; lactation and menopause; Infectious disease; inflammatory disease; Cushing's syndrome; adrenal gland tumor; hypothyroidism; increased prolactinemia; acromegaly; diabetes and cancer; Hormone therapy over the past three months; Taking antioxidant supplements over the past three months, Drug use over the past three months includes contraceptives; glucocorticoids; lipid-lowering drugs and weight loss drugs.

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
It will be done randomly using lottery method. Each patient will receive a number or code, and then we will write the numbers on pieces of paper. We will then place the pieces of paper in a container and select the samples according to the sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description

Supplements and placebo will be placed in similar containers and encode by someone except 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

2021-12-19, 1400/09/28

Ethics committee reference number

IR.QUMS.REC.1400.370

Health conditions studied

1

Description of health condition studied

Poly cystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

2

Description

Insulin

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**

Lipid profile

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

5**Description**

Total antioxidant capacity

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

6**Description**

Malondialdehyde

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

7**Description**

Inflammatory factors

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

8**Description**

Sex hormones include FSH, LH and testosterone

Timepoint

Before intervention and after intervention

Method of measurement

Eliza

9**Description**

Anti-Müllerian hormone

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

10**Description**

Sleep quality

Timepoint

Before intervention and after intervention

Method of measurement

Petersburg's sleep quality questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Oleoylethanolamide, a capsule 200 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

Placebo

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. Seyyed Mehdi Mirhashemi

Street address

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mirhashemism@gmail.com

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

No - There is not 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

y contacting the email address of a person responsible
for general inquiries

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**

After consulting with the research team, the data will be
provided to the applicant, which will probably be a one-
month process.

Comments