Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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-Mullerian 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
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Iran (Islamic Republic of)
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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
Street address
Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin
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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
Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

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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