

# 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)

##### Phone

+98 28 3375 2135

##### Email address

khadem.h@ajums.ac.ir

#### 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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**Email**

khademnut@yahoo.com

**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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### **Email**

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 scientific inquiries**

### **Contact**

#### **Name of organization / entity**

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#### **Full name of responsible person**

Hossein Khadem Haghighian

#### **Position**

Faculty member

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## **Person responsible for updating data**

### **Contact**

#### **Name of organization / entity**

Qazvin University of Medical Sciences

#### **Full name of responsible person**

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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**