

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### **Assessment of the ellagic acid supplementation effect on insulin resistance, oxidative stress and sex hormones levels in women with the Polycystic ovary syndrome.**

#### **Protocol summary**

##### **Study aim**

Determination of ellagic acid supplement effect in women with polycystic ovarian syndrome

##### **Design**

In this study, 60 patients with the polycystic 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 ellagic acid supplement as a randomized, double-blind clinical trial on patients with polycystic ovary syndrome referring to the specialized department of the hospital of Qazvin University of Medical Sciences. People with polycystic 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; Having a 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 ellagic acid (200mg daily) Control group: placebo group

##### **Main outcome variables**

Fasting blood sugar, insulin resistance, lipid profile,

oxidative stress indices, inflammatory factors, sex hormones, and Anti-Müllerian hormone.

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20141025019669N12**

Registration date: **2019-07-07, 1398/04/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-13, 1399/01/25**

Update count: **1**

##### **Registration date**

2019-07-07, 1398/04/16

##### **Registrant information**

##### **Name**

Hossein Khadem Haghghian

##### **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**

2019-05-31, 1398/03/10

##### **Expected recruitment end date**

2019-08-21, 1398/05/30

##### **Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Assessment of the ellagic acid supplementation effect on insulin resistance, oxidative stress and sex hormones levels in women with the Polycystic ovary syndrome.

**Public title**

Ellagic acid supplementation in women with the polycystic ovarian syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women with the polycystic ovarian syndrome

**Exclusion criteria:**

Use of contraceptives, glucocorticoids and lipid lowering drugs over the past three months

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **60**

**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 encoded 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**

2019-05-12, 1398/02/22

**Ethics committee reference number**

IR.QUMS.REC.1398.033

**Health conditions studied****1****Description of health condition studied**

Polycystic 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**

Total antioxidant capacity

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Eliza

**5**

**Description**

Malondialdehyde

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Eliza

**6**

**Description**

Inflammatory factors

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Eliza

**7**

**Description**

Sex hormones

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Eliza

**8**

**Description**

Anti-Müllerian hormone

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Eliza

**9**

**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: Ellagic acid, 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**

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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**Postal code**

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**Phone**

+98 28 3333 6001

**Email**

khademnut@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr. Peimani

**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****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

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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**

By 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

**What processes are involved for a request to access data/document**

Six months after the study  
**Comments**