

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

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

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

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

khademnut@yahoo.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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Phone

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Email

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

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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