Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Dec 2023

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 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
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 poly cystic ovarian syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women with the poly cystic 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 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
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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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. Peimani

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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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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