

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Effect of grape seed extract (GSE) supplementation on serum levels of androgens, gonadotropins and high sensitivity c-reactive protein in women with polycystic ovary syndrome (PCOS)

Protocol summary

Study aim

Effect of grape seed extract (GSE) supplementation on serum levels of androgens, gonadotropins and high sensitivity c-reactive protein in women with polycystic ovary syndrome (PCOS)

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, 50 patients with polycystic ovary syndrome.

Settings and conduct

This clinical trial-double blind is conducted in Imam Khomeini Hospital, Ahvaz

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 25 years to pre-menopause, body mass index less than or equal to 30, diagnosis of PCOS according to the Rotterdam criteria and diagnosis of a gynecologist. Inclusion criteria: unwillingness of patients to participate in the study, suffering from kidney diseases, coronary arteries, acute and chronic pulmonary inflammation, short bowel syndrome, allergies, pregnancy and breastfeeding, traveling for more than 2 weeks, smokers, use of supplements Food and anti-inflammatory drugs, use of any antioxidant supplements in the last 3 months, use of immunosuppressive drugs, following special diets, changing diet or deciding to lose weight, taking hormonal drugs

Intervention groups

ذخیره کردن ترجمه The intervention group received a daily supplement of 250 mg of grape seed extract (GSE) for 8 weeks. The control group received a placebo daily for 8 weeks.

Main outcome variables

testosterone, prolactin, Luteinizing Hormone (LH), Follicle-Stimulating Hormone (FSH), Fasting insulin, fasting blood sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220921056011N1**

Registration date: **2022-10-20, 1401/07/28**

Registration timing: **prospective**

Last update: **2022-10-20, 1401/07/28**

Update count: **0**

Registration date

2022-10-20, 1401/07/28

Registrant information

Name

marzie zilae

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3311 2713

Email address

marziezilae67@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of grape seed extract (GSE) supplementation on serum levels of androgens, gonadotropins and high sensitivity c-reactive protein in women with polycystic ovary syndrome (PCOS)

Public title

Effect of grape seed extract (GSE) supplementation on serum levels of androgens, gonadotropins and high sensitivity c-reactive protein in women with polycystic ovary syndrome (PCOS)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 25 to pre-menopause BMI<=30 Diagnosis of PCOS based on the Rotterdam criteria and the diagnosis of a gynecologist

Exclusion criteria:

Age

From **25 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked Randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

The type of treatment is selected by numbering in the envelope. participates and researcher are not informed. Elsewhere, the numbers are computerized to determine whether the number is grape seed extract supplement or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jondishapur University of Medical Sciences

Street address

Golstan

City

Ahavz

Province

Khouzestan

Postal code

15794 - 61357

Approval date

2022-07-16, 1401/04/25

Ethics committee reference number

IR.AJUMS.REC.1401.158

Health conditions studied

1

Description of health condition studied

Polycystic Ovary Syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Body mass index

Timepoint

before the start of the intervention and 8 weeks after taking the supplement

Method of measurement

ترازو

2

Description

Waist-Hip Ratio (WHR)

Timepoint

before the start of the intervention and 8 weeks after taking the supplement

Method of measurement

Meter

3

Description

testosterone

Timepoint

before the start of the intervention and 8 weeks after taking the supplement

Method of measurement

ELISA kit

4

Description

prolactin

Timepoint

before the start of the intervention and 8 weeks after taking the supplement

Method of measurement

ELISA kit

5

Description

Luteinizing Hormone (LH)

Timepoint

before the start of the intervention and 8 weeks after taking the supplement

Method of measurement

ELISA kit

6

Description

Follicle-Stimulating Hormone (FSH)

Timepoint

before the start of the intervention and 8 weeks after taking the supplement

Method of measurement

ELISA kit

7

Description

Fasting insulin

Timepoint

before the start of the intervention and 8 weeks after taking the supplement

Method of measurement

ELISA kit

8

Description

Homeostatic Model Assessment for Insulin Resistance

Timepoint

before the start of the intervention and 8 weeks after taking the supplement

Method of measurement

Formula

9

Description

fasting blood sugar

Timepoint

before the start of the intervention and 8 weeks after taking the supplement

Method of measurement

ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They take a daily supplement of 250 mg of grape seed extract (GSE) for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: They take a placebo supplement daily for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Marzie Zilaiee

Street address

Azadegan

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61936 73111

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hemam@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Email

info@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

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**

Ahvaz University of Medical Sciences

Full name of responsible person

Marzie Zilaiee

Position

Assistant Professor

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

Yes - There is 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

Part of the data, such as the information related to the main outcome, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Using the data to complete the research process regarding the effects of grape seed extract supplementation on the serum levels of androgens, gonadotropes, and high-sensitivity C-reactive protein in women with polycystic ovary syndrome.

From where data/document is obtainable

Contact the email of the Corresponding author of the

article resulting from the data of the research project.
What processes are involved for a request to access data/document

Contact the email of the Corresponding author of the article resulting from the data of the research project.
Comments