

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

The Effect of Grape Seed Extract (GSE) Supplementation on Fasting Blood Sugar Status, Insulin Resistance and Lipid Profile in Women with Polycystic Ovary Syndrome (PCOS)

Protocol summary

Study aim

The effect of grape seed extract (GSE) supplementation on fasting blood sugar status, insulin resistance and lipid profile in women with polycystic ovary syndrome

Design

Patients (n = 50) were randomly divided into 2 groups of 25. The intervention group daily consumes a 250mg grape seed extract (GSE) supplement for 8 weeks. Patients in the control group daily take one 250mg of placebo that is complementary in terms of color and size. Grape Core Extract Supplement (GSE) from Shari Dar (Iran) Co. To assess the biochemical properties of 10cc fasting blood samples, 10 to 12 hours of fasting will be collected at the beginning and end of the study. In this intervention, blood sampling will be carried out by a qualified laboratory scientist. Samples are separated at a maximum of 1 hour for 10 minutes with 2000 rounds and serum. The plasma and serum samples were stored in a freezer, and transferred to the Snijders Scientific Freezer Hospital for a few days, and kept there until the tests were performed. The serum will be used to carry out biochemical tests for fasting blood glucose, lipid profile, and insulin.

Settings and conduct

Golestan Hospital ahwaz

Participants/Inclusion and exclusion criteria

Entry criteria: Age 25 to 60 years, Body mass index less than or equal to 30, PCOS diagnosis, defined as the presence of 2 attributes of the following 3 characteristics: oligo-evolution or non-ovulation, biochemical and / or clinical evidence of hyperandrogenism, features Transvaginal ultrasonography, representing more than 12 immature follicles less than 10 mm per ovary

Intervention groups

The intervention group daily consumes a 250 mg grape seed extract (GSE) supplement for 8 weeks.

Main outcome variables

The starting point in the cognitive process is to use one of the nutrition management strategies for this disease in further research.

General information

Reason for update

Acronym

GSE-PCOS

IRCT registration information

IRCT registration number: **IRCT20190122042458N1**

Registration date: **2019-09-04, 1398/06/13**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-04, 1398/06/13**

Update count: **0**

Registration date

2019-09-04, 1398/06/13

Registrant information

Name

pegahe sedighii

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3360 5280

Email address

amiraryan89@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-11, 1398/04/20

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Grape Seed Extract (GSE) Supplementation on Fasting Blood Sugar Status, Insulin Resistance and Lipid Profile in Women with Polycystic Ovary Syndrome (PCOS)

Public title

The Effect of Grape Seed Extract Supplementation on Fasting Blood Sugar Status, Insulin Resistance and Lipid Profile in Women with Polycystic Ovary Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of Admission 25 to 60 Years Body Mass Index Less than or Equal to 30 Diagnosis of Women with Polycystic Ovarian Syndrome Defined as Presence of 2 Characteristics of the Following 3 Characteristics: Oligoavulation or non Ovulation, Biochemical and / or Clinical Evidence of Hyperandrogenism, Features of Transvaginal Ultrasonography Representing More than 12 Immature Follicles Less than 10 mm Per Ovary

Exclusion criteria:

Unwillingness of Patients to Participate in the Study Kidney Disease, Coronary Arteries, Acute and Chronic Pulmonary Inflammation, Short Stomach and Intestine Syndrome, Allergies Pregnancy and Lactation Traveling for More than 2 Weeks Smokers Use of Food Supplements Anti-Inflammatory Drugs Use of any Antioxidant Supplement in the Last 3 Months Use of Immunosuppressive Drugs Follow Certain Diets Change the Diet or Decide to Lose Weight

Age

From **25 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Participants Do not know Which Control Groups or Witness Group are Located. Investigator and Attending

Medical Personnel and Data Collectors Do not know the Presence of Participants In the Witness Group or Control Group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

IR.AJUMS.REC.1398.236

Street address

Golestan -hospital

City

Ahwaz

Province

Khouzestan

Postal code

1853913336

Approval date

2019-06-24, 1398/04/03

Ethics committee reference number

IR.AJUMS.REC.1398.236

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

Polycystic Ovary Syndrome(PCOS)

ICD-10 code

P05.08

ICD-10 code description

Newborn light for gestational age, 2000-2499 grams

Primary outcomes**1****Description**

HDL

Timepoint

0-60

Method of measurement

Laboratory Kits

2**Description**

LDL

Timepoint

0-60

Method of measurement

Laboratory Kits

3

Description

T.G

Timepoint

0-60

Method of measurement

Laboratory Kits

4

Description

FBS

Timepoint

0-60

Method of measurement

Laboratory Kits

5

Description

Insulin resistance

Timepoint

0-60

Method of measurement

Laboratory Kits

6

Description

Insulin

Timepoint

0-60

Method of measurement

Laboratory Kits

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Includes 25 Patients Who Will be Randomly Selected and Treated With Placebo Orally For Two Months.

Category

Placebo

2

Description

Control Group: Includes 25 Patients Who Will be Treated With Grape Seed Dupplements For Two Months, Supplemented By Grape Seed Purchased From Shari Drug Company, Which Will Be Given 250 mg Orally Daily.

Category

Diagnosis

Recruitment centers

1

Recruitment center**Name of recruitment center**

Golestani Hospital, ahwaz

Full name of responsible person

Pegah Sedighii

Street address

Golestani Hospital, Ahwaz

City

Ahwaz

Province

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Postal code

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+98 21 3360 5280

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Email

Amiraryan89@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Pegah Sedighi

Street address

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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

Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Pegah Sedighii
Position
Master of Science (MSc)
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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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

No - There is not 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

After Collecting the Data in the Form of the Final Report of the Dissertation, it Will be Available to Ahvaz University of Medical Sciences.

When the data will become available and for how long

Start of Access 3 Months After Printing Results

To whom data/document is available

Project Implementers

Under which criteria data/document could be used

Based on the laws of Ahwaz University of Medical Sciences

From where data/document is obtainable

Ahvaz University of Medical Sciences

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

Ahvaz University of Medical Sciences Assistant Professor of Nutrition

Comments