Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 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
Khouzestan
Postal code
1853913336
Phone
+98 21 3360 5280
Fax
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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
Golestani Hospital, Ahvaz
City
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Province
Khouzestan
Postal code
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Fax
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Email
amiraryan89@yahoo.com
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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Pegah Sedighii

Position

Master of Science (MSc)

Latest degree

Bachelor

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Nutrition

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Email

amiraryan89@yahoo.com

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 Ahwaz 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

Ahwaz University of Medical Sciences

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

Ahwaz University of Medical Sciences Assistant Professor of Nutrition

Comments