Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effects of resveratrol supplementation on hormonal, inflammatory and metabolic in women with PCOS.

Protocol summary

Summary

The purpose of this study is to investigate the effects of resveratrol supplement on metabolic factors in PCOS patients. 80 patients with PCOS (according to Androgen Excess Society criteria)and don’t have thyroid disease and androgenic hormone secretor tumors between the age range of 18-40 will be randomly assigned to groups that received either resveratrol or placebo (one time a day) for 12 weeks. FSH, LH, SHBG, fasting blood sugar, insulin, HDL, LDL-C, total cholesterol, triglycerides ,blood pressure, body composition will be measured before and 12 weeks after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061917139N2**
Registration date: **2017-07-17, 1396/04/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-07-17, 1396/04/26

Registrant information

Name
Mohammad Reza Mohajeri-tehrani
Name of organization / entity
Endocrinology and Metabolism Research Institute
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

EMRI & Alborz University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of resveratrol supplementation on hormonal, inflammatory and metabolic in women with PCOS.

Public title

The effect of resveratrol on PCOS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: PCOS diagnosis (according to Androgen Excess Society criteria); hyperandrogenism (hirsutism) / hyperandrogenemia (testosterone >70ng/dl) and/or oligomenorrhea (<8 spontaneous menses per year) and/or polycystic ovarian morphology on ultrasound Women aged from 18 to 40 years old; Normal prolactin; normal thyroid function; 17-OH progesterone; No evidence of Androgenic hormone secretor tumors; Cushing's syndrome or acromegaly Exclusion criteria: Use of either oral contraceptives, steroids hormones or other medications that could modify the metabolism 3 months before the onset of the trial.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Alborz University of Medical Sciences
Street address
Educational Department, Alborz University of Medical Sciences, North Taleqani Blvd, Taleqani Square, Karaj
City
Karaj
Postal code
Approval date
2017-03-13, 1395/12/23
Ethics committee reference number
Abzums.rec.1395.135

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
(S.H.B.G) Sex Hormon Binding Globolin
Timepoint
Before and 12 weekes after the intervention
Method of measurement
-

2

Description
FSH
Timepoint
Before and 6 weekes after the intervention
Method of measurement
ng/ml

3

Description
LH
Timepoint
Before and 6 weekes after the intervention
Method of measurement
ng/ml

4

Description
Fasting blood sugar
Timepoint
Before and 6 weekes after the intervention
Method of measurement
mg/dl

5

Description
testosterone
Timepoint
Before and 12 weekes after the intervention
Method of measurement
ng/ml

6

Description
DHEA-S
Timepoint
Before and 12 weekes after the intervention
Method of measurement
nmol/L

Secondary outcomes

1

Description
HDL- cholesterol
Timepoint
Before and 12 weekes after the intervention
Method of measurement
mg/dl

2

Description
HOMA-insulin resistance
Timepoint
Before and 12 weekes after the intervention
Method of measurement

-

3

Description
Hs-CRP
Timepoint
Before and 12 weekes after the intervention
Method of measurement
mg/dl

4

Description
c-peptide
Timepoint
Before and 12 weekes after the intervention
Method of measurement
mg/dl

5

Description
LDL-Cholesterol
Timepoint
Before and 12 weekes after the intervention
Method of measurement
mg/dl

6

Description
Creatinine
Timepoint
Before and 12 weekes after the intervention
Method of measurement
mg/dl

7

Description
total serum cholesterol
Timepoint
Before and 12 weekes after the intervention
Method of measurement
mg/dl

8

Description
TG
Timepoint
Before and 12 weekes after the intervention
Method of measurement
mg/dl

9

Description
Body composition (FM,FFM)
Timepoint
Before and 12 weekes after the intervention
Method of measurement
%

10

Description
insulin levels
Timepoint
Before and 12 weekes after the intervention
Method of measurement
mU/ml

11

Description
HbA1C
Timepoint
Before and 12 weekes after the intervention
Method of measurement
%

12

Description
Weight
Timepoint
Before and 12 weekes after the intervention
Method of measurement
kg

Intervention groups

1

Description
Resveratrol(one time a day)
Category
Treatment - Drugs

2

Description
placebo(maltodextrin) one time a day
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
EMRI
Full name of responsible person
Mohammad Reza Mohajeri-Tehrani
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

EMRI

Full name of responsible person
Mostafa Qorbani

Street address
Endocrinology & Metabolism Research Institute, 5th floor, Shariati Hospital, North Kargar Avenue

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
EMRI

Proportion provided by this source

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

2

Sponsor

Name of organization / entity
Alborz University of Medical Sciences

Full name of responsible person
Mostafa Qorbani

Street address
Alborz University of Medical Sciences, North Taleqani Blvd, Taleqani Square, Karaj, Islamic Republic of Iran

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Alborz University of Medical Sciences

Proportion provided by this source

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
EMRI

Full name of responsible person
Mostafa Qorbani

Position
assistant professor

Other areas of specialty/work

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MD

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Person responsible for updating data

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PhD student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty