

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)

Phone

+98 21 8822 0071

Email address

mrmohajeri@tums.ac.ir

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 weeks after the intervention

Method of measurement

ng/ml

3

Description

LH

Timepoint

Before and 6 weeks after the intervention

Method of measurement

ng/ml

4

Description

Fasting blood sugar

Timepoint

Before and 6 weeks 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 weeks after the intervention

Method of measurement

mg/dl

4

Description

c-peptide

Timepoint

Before and 12 weeks after the intervention

Method of measurement

mg/dl

5

Description

LDL-Cholesterol

Timepoint

Before and 12 weeks after the intervention

Method of measurement

mg/dl

6

Description

Creatinine

Timepoint

Before and 12 weeks after the intervention

Method of measurement

mg/dl

7

Description

total serum cholesterol

Timepoint

Before and 12 weeks after the intervention

Method of measurement

mg/dl

8

Description

TG

Timepoint

Before and 12 weeks after the intervention

Method of measurement

mg/dl

9

Description

Body composition (FM,FFM)

Timepoint

Before and 12 weeks after the intervention

Method of measurement

%

10

Description

insulin levels

Timepoint

Before and 12 weeks after the intervention

Method of measurement

mU/ml

11

Description

HbA1C

Timepoint

Before and 12 weeks after the intervention

Method of measurement

%

12

Description

Weight

Timepoint

Before and 12 weeks 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
Street address
 Endocrinology & Metabolism Research Institute, 5th floor, Shariati Hospital, North Kargar Avenue, Tehran, 1411413137, Iran
City
 Tehran
Postal code
Phone
 +98 21 8822 0071
Fax
Email
 mqorbani1379@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
 EMRI
Full name of responsible person
 Mohammad Reza Mohajeri-Tehrani
Position
 MD
Other areas of specialty/work
Street address
 Endocrinology & Metabolism Research Institute, 5th floor, Shariati Hospital, North Kargar Avenue, Tehran, 1411413137,Iran
City
 Tehran
Postal code
Phone
 +98 21 8822 0071
Fax
Email
 mrmohajeri@tums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
 EMRI
Full name of responsible person
 Asieh Mansour
Position
 PhD student
Other areas of specialty/work
Street address
 Endocrinology & Metabolism Research Institute, 5th floor, Shariati Hospital, North Kargar Avenue, Tehran, 1411413137,Iran
City
 Tehran
Postal code
Phone
 00

Fax
Email
asiehmansour@yahoo.com
Web page address

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