# 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 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**

**Street address**
Endocrinology & Metabolism Research Institute, 5th floor, Shariati Hospital, North Kargar Avenue, Tehran, 1411413137, Iran

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mqorbani1379@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

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MD

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Endocrinology & Metabolism Research Institute, 5th floor, Shariati Hospital, North Kargar Avenue, Tehran, 1411413137,Iran

**City**
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**Postal code**

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+98 21 8822 0071

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## Person responsible for updating data

**Contact**

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**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**
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**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*