

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The effects of Resveratrol on expression of main ovarian angiogenesis genes (VEGF & HIF-1) & androgene aromatization gene (CYP19) in granulosa cells of PCOS patients and their IVF outcomes.

#### Protocol summary

##### Summary

This is a triple-blind RCT study. The ART (ICSI) candidate PCOS patients, firstly confirm their syndrome based on Rotterdam Criterion. The patients that full fill the inclusion criteria will sign the consent informed form. 40 patients randomly assigned equally to two groups for Resveratrol (Intervention) & Placebo (Control) groups. All patients take the Resveratrol/placebo 1 gr/day for 40 days from the beginning of their menstruation cycle till oocyte retrieval in OR room. Expression of the CYP19, VEGF & HIF-1 will quantify by the real-time PCR (SYBR green). Finally, The sexual hormones & Fertility outcomes of the patients (like; oocytes quality, number of oocytes, fertilization rate, cleavage rate, embryos quality, number of embryos & chemical pregnancy rate) will be assessed and compromised in two groups.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2016030126860N1**  
Registration date: **2016-03-15, 1394/12/25**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-03-15, 1394/12/25

##### Registrant information

###### Name

Mojdeh Bahramrezaie

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4438 2693

###### Email address

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###### Recruitment status

**Recruitment complete**

###### Funding source

Governmental- Tehran University of Medical Sciences.

###### Expected recruitment start date

2016-04-03, 1395/01/15

###### Expected recruitment end date

2017-04-21, 1396/02/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

The effects of Resveratrol on expression of main ovarian angiogenesis genes (VEGF & HIF-1) & androgene aromatization gene (CYP19) in granulosa cells of PCOS patients and their IVF outcomes.

###### Public title

The effects of Resveratrol on PCOS.

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion Criteria: Infertility with documented PCOS & Hyperandrogenism; 18-40 Y/O; Candidate for IVF Cycle; If have male factor; it must mild to moderate form, not non-obstructive azospermia; If have other female factor; only cervical & tubal factors are acceptable. Exclusion Criteria: FSH>10; Severe endometriosis (Stage III or IV); Cushing Syndrome; Hyperprolactinemia; Thyroid

diseases; Ovarian Tumors; Severe male factor like non-Obstructive Azospermia; Steroids & OCP taking History in past 3 months; SLE (Systemic Lupus Erythematosus) & autoimmune diseases; Systemic diseases like Metabolic Syndrome, Hyperlipidemia, Diabetes & cardiovascular diseases; Diseases due to malnutrition & obesity with unknown cause.

#### Age

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

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences ethical committee

##### Street address

Tehran, Poursina St.

##### City

Tehran

##### Postal code

#### Approval date

2016-01-19, 1394/10/29

#### Ethics committee reference number

IR.TUMS.REC.1394.1690

## Health conditions studied

### 1

#### Description of health condition studied

Polycystic ovarian syndrome (PCOS)

#### ICD-10 code

E28.2

#### ICD-10 code description

Polycystic ovarian syndrome

## Primary outcomes

### 1

#### Description

CYP19 Expression

#### Timepoint

After follicle retrieval (Approximately 40 days after treatment)

#### Method of measurement

Real-time relative quantification

### 2

#### Description

VEGF Expression

#### Timepoint

After follicle retrieval (Approximately 40 days after treatment)

#### Method of measurement

Real-time relative quantification

### 3

#### Description

HIF-1 Expression

#### Timepoint

After follicle retrieval (Approximately 40 days after treatment)

#### Method of measurement

Real-time relative quantification

### 4

#### Description

Sexual hormones (Including; FSH, LH, Estradiol, TSH, Prolactin, Progesterone, Testosterone & AMH)

#### Timepoint

Before & After Intervention

#### Method of measurement

By IFA Method

### 5

#### Description

Number of retrieved Oocytes

#### Timepoint

After Intervention

#### Method of measurement

Count Under Microscope

### 6

#### Description

Number of retrieved Mature Oocytes (MII)

#### Timepoint

After Intervention

#### Method of measurement

Count Under Microscope

### 7

#### Description

Quality of Retrieved Oocytes

**Timepoint**

After Intervention

**Method of measurement**

Based on WHO Criteria

**8**

**Description**

Number of fertilized eggs

**Timepoint**

After Intervention

**Method of measurement**

Based on No. of 2PN oocytes

**9**

**Description**

Fertilization rate

**Timepoint**

After Intervention

**Method of measurement**

fertilized egg number divided to retrieved oocyte number

**10**

**Description**

Number of Cleavage embryos

**Timepoint**

After Intervention

**Method of measurement**

Count the Cleavage (8 Cells) embryos

**11**

**Description**

Cleavage rate

**Timepoint**

After Intervention

**Method of measurement**

embryo number divided to fertilized egg number

**12**

**Description**

High Quality Embryo Rate

**Timepoint**

After Intervention

**Method of measurement**

Count the Grade 1&2 of embryo quality

**13**

**Description**

Chemical Pregnancy Rate

**Timepoint**

After Intervention

**Method of measurement**

B-hCG test

**14**

**Description**

Clinical Pregnancy Rate

**Timepoint**

After Intervention

**Method of measurement**

Gestational Sac in Ultrasound

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

For Intervention Group: Resveratrol, Orally 1gr/day (2 Cap.) for 40 days from the beginning of the menstruation cycle till oocyte retrieval.

**Category**

Treatment - Drugs

**2**

**Description**

For Control Group: Placebo of Resveratrol, Orally 2 Cap. for 40 days from the beginning of the menstruation cycle till oocyte retrieval.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Sarem Women's Hospital

**Full name of responsible person**

Mrs. Shami

**Street address**

Phase-3 Shahrak-e-Ekbatan

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Masud Yunesian

**Street address**

Poursina st.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran University of Medical Sciences

**Proportion provided by this source**

100

**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**

Tehran University of Medical sciences

**Full name of responsible person**

Mojdeh Bahramrezaie

**Position**

PhD Student

**Other areas of specialty/work****Street address**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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*