

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The effects of Resveratrol on expression of some ER stress pathway genes in granulosa cells and some circulating inflammatory markers in PCOS patients

#### 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 ATF4, ATF6, CHOP, GRP78, XBP1 in granulosa cells and expression of the NF- $\kappa$ B in polymorphonuclear cells will quantify by the real-time PCR (SYBR green). Finally, some circulating inflammatory factors (IL-6, IL-18, IL-1beta, TNF-alpha, CRP), insulin resistance factors( glucose, insulin, homosyctein, HOMA-IR, QUICKI), some biochemical factors( LDL, HDL, Trigliseride, cholestrole, FBS) and also ROS(PC & MD) and TAC in serum and follicular fluid will be assessed and compromised in two groups. Fertility outcomes of the patients (like; oocytes quality, number of oocytes, fertilization rate, cleavage rate, embryos quality, number of embryos, chemical and clinical pregnancy rate) will be assessed and compromised in two groups.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2016041827453N1**  
Registration date: **2016-05-25, 1395/03/05**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-25, 1395/03/05

##### Registrant information

###### Name

Samaneh Brenjian

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2200 5217

###### Email address

sbrenjian@razi.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Governmental- Tehran University of Medical Sciences.

##### Expected recruitment start date

2016-05-04, 1395/02/15

##### Expected recruitment end date

2017-05-22, 1396/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of Resveratrol on expression of some ER stress pathway genes in granulosa cells and some circulating inflammatory markers in PCOS patients

##### Public title

The effects of Resveratrol on PCOS.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: Infertility with documented PCOS based on Rotterdam criteria; 18-40 Y/O; If have male factor; it must be mild to moderate form, not non-obstructive azospermia; If have other female factor; only cervical & tubal factors are acceptable; Candidate for IVF Cycle; No insulin taking history; Not eating red grapes, pistachio, peanut and berries recently. Exclusion Criteria: Diseases due to obesity with unknown cause (Hypothyroidism, Cushing Syndrome); . FSH>10 at third day of the cycle; Severe endometriosis (Stage III or IV); Thyroid diseases; Congenital Adrenal Hyperplasia; Hyperprolactinemia; Ovarian Tumors; Taking Steroids, OCP and other drugs that affect ovarian function, insulin sensitivity or lipid metabolism in past 3 months (except routine PCOS therapy); SLE (Systemic Lupus Erythematosus) & autoimmune diseases; Systemic diseases like Metabolic Syndrome, Hyperlipidemias & cardiovascular diseases; Severe male factor like non-Obstructive Azospermia (sperm concentration < 5 mill/m); Patients who use vitrification method to avoid OHSS; Having allergy to some fruits like red grapes, pistachio and red berry; Insulin taking history

**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**

-Randomized Controlled Trial

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Tehran, Poursina St.

**City**

Tehran

**Postal code****Approval date**

2016-01-27, 1394/11/07

**Ethics committee reference number**

IR.TUMS.REC.1394.1755

**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**

ATF4 Expression

**Timepoint**

After follicle retrieval (Approximately 40 days after treatment)

**Method of measurement**

Real-time relative quantification

**2****Description**

ATF6 Expression

**Timepoint**

After follicle retrieval (Approximately 40 days after treatment)

**Method of measurement**

Real-time relative quantification

**3****Description**

CHOP Expression

**Timepoint**

After follicle retrieval (Approximately 40 days after treatment)

**Method of measurement**

Real-time relative quantification

**4****Description**

GRP78 Expression

**Timepoint**

After follicle retrieval (Approximately 40 days after treatment)

**Method of measurement**

Real-time relative quantification

**5****Description**

XBP1 Expression

## **Timepoint**

After follicle retrieval (Approximately 40 days after treatment)

## **Method of measurement**

Real-time relative quantification

## **6**

### **Description**

inflammatory factors(IL-6, IL-18, IL-1beta, TNF-alpha, CRP)

### **Timepoint**

Before & After Intervention

### **Method of measurement**

By ELISA Method

## **7**

### **Description**

Insulin Resistance factors( glucose, insulin, homocystein, QUICKI, HOMA-IR)

### **Timepoint**

Before & After Intervention

### **Method of measurement**

By Espectrophotometry Method

## **8**

### **Description**

Biochemical Factors( FBS, cholestrole, Trigliseride, HDL, LDL)

### **Timepoint**

Before & After Intervention

### **Method of measurement**

By Photometry Method

## **9**

### **Description**

ROS (Reactive Oxygen Species: PC & MD)

### **Timepoint**

After follicle retrieval (Approximately 40 days after treatment) , Before & After Intervention

### **Method of measurement**

By Espectrophotometry Method

## **10**

### **Description**

NF-κB Expression

### **Timepoint**

Before & After Intervention

### **Method of measurement**

Real-time relative quantification

## **11**

### **Description**

TAC (Total Antioxidant Capacity)

### **Timepoint**

After follicle retrieval (Approximately 40 days after treatment) , Before & After Intervention

### **Method of measurement**

By Espectrophotometry Method

## **12**

### **Description**

Number of retrieved Oocytes

### **Timepoint**

After Intervention

### **Method of measurement**

Count Under Microscope

## **13**

### **Description**

Number of retrieved Mature Oocytes (MII)

### **Timepoint**

After Intervention

### **Method of measurement**

Count Under Microscope

## **14**

### **Description**

Quality of Retrieved Oocytes

### **Timepoint**

After Intervention

### **Method of measurement**

Based on WHO Criteria

## **15**

### **Description**

Number of fertilized eggs

### **Timepoint**

After Intervention

### **Method of measurement**

Based on No. of 2PN oocytes

## **16**

### **Description**

Fertilization rate

### **Timepoint**

After Intervention

### **Method of measurement**

fertilized egg number divided to retrieved oocyte number

## **17**

### **Description**

Number of Cleavage embryos

### **Timepoint**

After Intervention

### **Method of measurement**

Count the Cleavage (8 Cells) embryos

## **18**

### **Description**

Cleavage rate

### **Timepoint**

After Intervention

### **Method of measurement**

embryo number divided to fertilized egg number

## 19

### Description

High Quality Embryo Rate

### Timepoint

After Intervention

### Method of measurement

Count the Grade 1&2 of embryo quality

## 20

### Description

Chemical Pregnancy Rate

### Timepoint

After Intervention

### Method of measurement

B-hCG test

## 21

### 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 (manufactured by Biovita company), 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

Arash Hospital

##### Full name of responsible person

##### Street address

Tehranpars second square

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of 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

Vice chancellor for research of 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

Samaneh Brenjian

##### Position

PhD Student

##### Other areas of specialty/work

##### Street address

Poursina st. Tehran University of Medical sciences, Anatomy & Reproductive Biology Department

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Web page address**

<http://tums.ac.ir/>

## 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*