

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### The effect of Resveratrol on the expression of the granulosa apoptosis-associated genes in polycystic ovary syndrome and its relationship with in vitro fertilization outcome

#### Protocol summary

##### Study aim

The effect of Resveratrol on the expression of some genes involved in the process of apoptosis in granulosa cells in patients with polycystic ovary syndrome and its relationship with the consequences of in vitro fertilization.

##### Design

Clinical trial with control and intervention group, with parallel groups, triple blind, randomized, phase 3 on 40 patients, random blocking was used for randomization.

##### Settings and conduct

Patients referred to infertility center of Hormozgan University of Medical Sciences who are included in the study underwent ovulation induction protocol (antagonist protocol). Granulosa cells will be collected and centrifuged on the day of ovulation. The cell pellete will be used to extract RNA. The expression of Survivin, Caspase 3, and Caspase7 genes will be evaluated using Real-time PCR.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with polycystic ovary syndrome based on Rotterdam criteria, Women of childbearing age between 18 and 40 years, Candidate for in vitro fertilization, Not receiving insulin Exclusion criteria: FSH > 10, high grade endometriosis (III and IV), thyroid diseases, congenital adrenal hyperplasia, hyperprolactinemia, ovarian secretion tumors, lupus and autoimmune diseases, the consumption of red grapes, pistachios, peanuts and berries, sensitivity to fruits such as red grapes, pistachios and strawberries, receiving insulin, diabetes mellitus, cushing's syndrome

##### Intervention groups

Intervention group: Receiving 40 days of resveratrol (800 mg once daily) from the beginning of the menstrual cycle until the day of ovulation Control group: receiving 40 days of placebo

##### Main outcome variables

Apoptosis, number of eggs, number of embryos, embryo quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200905048630N1**

Registration date: **2020-09-21, 1399/06/31**

Registration timing: **prospective**

Last update: **2020-09-21, 1399/06/31**

Update count: **0**

##### Registration date

2020-09-21, 1399/06/31

##### Registrant information

##### Name

Ensieh Salehi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 76 3333 0755

##### Email address

salehiensieh@hums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-21, 1399/10/01

##### Expected recruitment end date

2022-03-21, 1401/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
The effect of Resveratrol on the expression of the granulosa apoptosis-associated genes in polycystic ovary syndrome and its relationship with in vitro fertilization outcome

**Public title**  
The effect of Resveratrol on the expression of the granulosa apoptosis-associated genes in polycystic ovary syndrome and its relationship with in vitro fertilization outcome

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Women with polycystic ovary syndrome based on Rotterdam criteria Women of childbearing age between 18 and 40 years Candidate for in vitro fertilization Not receiving insulin  
**Exclusion criteria:**

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

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Eligible patients (including 40 patients) are randomly assigned by a statistical expert using a simple randomization method. In this method, the Random between function of Excell program is used to generate a random number between 1 and 2. This is repeated 40 times and therefore a random sequence is obtained.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
Participants, research assistants, and investigators were masked to treatment allocation.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

##### Street address

Shahid Mohammadi Hospital, Shafa Alley, Jomhuri Boulevard

##### City

Bandar Abbas

##### Province

Hormozgan

##### Postal code

7916613885

##### Approval date

2020-08-02, 1399/05/12

##### Ethics committee reference number

IR.HUMS.REC.1399.234

## 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

Apoptosis

#### Timepoint

40 days after the beginning of the intervention

#### Method of measurement

real time pcr

## Secondary outcomes

### 1

#### Description

Egg numbers

#### Timepoint

40 days after the beginning of the intervention

#### Method of measurement

Counting

### 2

#### Description

Number of embryos

#### Timepoint

43 days after the beginning of the intervention

## Method of measurement

Counting

### 3

#### Description

Number of good quality embryo

#### Timepoint

43 days after the beginning of the intervention

#### Method of measurement

Counting

## Intervention groups

### 1

#### Description

Intervention group: from the beginning of the cycle, individuals in this group will receive one 99% pure trans-Resveratrol capsule (800 mg per day) as orally purchased from the US company Mega Resveratrol.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: from the beginning of the cycle, individuals in this group will receive one placebo capsule per day as orally purchased from the US company Mega Resveratrol.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Infertility center of Hormozgan university of medical sciences

##### Full name of responsible person

Ensieh salehi

##### Street address

Shahid Mohammadi Hospital, Infertility Center, Shafa Alley, Jomhuri Boulevard

##### City

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##### Phone

+98 76 3334 7001

##### Email

salehiensieh@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bandare-abbas University of Medical Sciences

##### Full name of responsible person

Dr. Teamur Aghamolaei

##### Street address

Shahid Mohammadi Hospital, Research Deputy, Jomhuri Boulevard

##### City

Bandar Abbas

##### Province

Hormozgan

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7916613885

##### Phone

+98 76 3333 3280

##### Email

research@hums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Bandare-abbas University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Bandare-abbas University of Medical Sciences

##### Full name of responsible person

Ensieh salehi

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Reproductive Biology

##### Street address

Fertility and Infertility research Center, Shahid Mohammadi Hospital, Shafa Alley, Jomhuri Boulevard

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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Bandare-abbas University of Medical Sciences

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**Latest degree**

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**Province**

Hormozgan

**Postal code**

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**Phone**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to  
make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to  
make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to  
make this available

**Title and more details about the data/document**

All data obtained in the research will be published in one  
of the valid and related scientific journals.

**When the data will become available and for how  
long**

2022

**To whom data/document is available**

Researchers working in academic institutions

**Under which criteria data/document could be used**

The data of this study can be used as an adjuvant  
therapy in patients with polycystic ovary syndrome  
underwent IVF/ICSI.

**From where data/document is obtainable**

Dr. Ensieh salehi salehiensieh@gmail.com

**What processes are involved for a request to access  
data/document**

By sending an email to the corresponding author.

**Comments**