

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### evaluation of resveratrol effect on the expression of the apoptosis-associated genes in granulosa cells of PCOS patients applicant to ART (triple-blinded randomized controlled trial)

#### Protocol summary

##### Study aim

evaluation of resveratrol effect on the expression of the apoptosis-associated genes in granulosa cells of PCOS patients applicant to artificial reproductive techniques (ART)

##### Design

A clinical trial with two groups of treatment and control (drug and placebo) with equal numbers in each group, triple-blind, randomized (table of random numbers) and concealed (code instead of people's names), phase 3 on a sample of 40 patients.

##### Settings and conduct

Admission is done in Shariati Hospital, Tehran, infertility ward. Patients participating in the experiment receive either medication or a placebo for 60 days leading up to the day of the egg pick-up operation. Both the patient and the research team only see the code or color of the drug package and do not know its content. The data analyst is also unaware of the study side of the subjects (either real drug or placebo).

##### Participants/Inclusion and exclusion criteria

inclusion criteria: diagnosed with PCOS; aged between 18 and 40 yo; exclusion criteria: pregnancy; adrenal hyperplasia; androgen-secreting tumors; hyperprolactinemia; thyroid malfunction; diabetes/glucose intolerance; male infertility factors; BMI > 30; taking anti-oxidant supplements, ovulation stimulating drugs and drugs with effect on hormone profile less than 6 months prior to entering the study.

##### Intervention groups

treatment group: containing 20 patients each taking 800mg of resveratrol in form of pills for 60 days in a row.  
control group: containing 20 patients taking similar pills without resveratrol substance for 60 days in a row.

##### Main outcome variables

expression of caspase3, 7 and survivin genes; ART outcomes; lipid profile, insulin and glucose; sex

hormones.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220815055705N1**

Registration date: **2023-11-16, 1402/08/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-11-16, 1402/08/25**

Update count: **0**

##### Registration date

2023-11-16, 1402/08/25

##### Registrant information

##### Name

Mohammadhosein Bagheri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3638 3391

##### Email address

mh-bagheri@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-23, 1402/08/01

##### Expected recruitment end date

2024-03-20, 1403/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

evaluation of resveratrol effect on the expression of the apoptosis-associated genes in granulosa cells of PCOS patients applicant to ART (triple-blinded randomized controlled trial)

**Public title**

Resveratrol effect on ART outcome

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

patients must be infertile due to PCOS and aged between 18 and 40. PCOS is diagnosed based on Rotterdam criteria and having 2 of 3 criteria is enough for diagnosis: amenorrhea or oligomenorrhea, clinical or biochemical hyperandrogenism manifestations, observation of cysts in ovary sonography (at least 12 follicles with diameter of 2 - 9 mm or an increase in ovary volume more than 10cm in trans-vaginal ultrasound radiography).

**Exclusion criteria:**

pregnancy adrenal hyperplasia androgen secreting tumors hyperprolactinemia thyroid malfunction diabetes/glucose intolerance male infertility factors BMI > 30 taking anti-oxidant supplements less than 6 months prior to entering the study. taking ovulation stimulating drugs less than 6 months prior to entering the study. taking drugs with effect on hormone profile less than 6 months prior to entering the study.

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

If patients meet the criteria of the study and sign an informed consent form they will be divided into two groups after referring to the infertility ward of the hospital. using the random block method and using a random number table (numbers 0 to 4 in group A and numbers 5 to 9 in group B). In this way, it is not known before the allocation of the individual of that person's group. In this method, each of the randomly obtained sequences is written on a card and the cards are placed in sealed envelopes respectively. In order to maintain a random sequence, each envelope is numbered in the

same order. Finally, the envelope is sealed and placed in a box. At the time of inclusion of eligible patients, one of the letter envelopes is opened and the allocated group of that patient is revealed. Hiding will also be done to prevent directional selection by replacing the names of people with code (numbers).

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The original drug and placebo will be divided into the same dose, number, and container and then determined by someone outside of the experiment by a different code or color. (The information contained in the envelope sealed will be kept with this person until the end of the experiment.) Patients who participated in the experiment without knowing the contents of the packages (drug or placebo) will receive one of the two packages and will be given as per instructions. None of the people involved in the study will be informed of the contents of the packages until the end of the data collection and analysis.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of shari'ati hospital

**Street address**

shari'ati hospital, jalal al ahmad st., jalal al ahmad hwy., jamshidieh district, tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713135

**Approval date**

2023-10-02, 1402/07/10

**Ethics committee reference number**

IR.TUMS.SHARIATI.REC.1402.103

**Health conditions studied****1****Description of health condition studied**

polycystic ovarian syndrome

**ICD-10 code**

E28.2

**ICD-10 code description**

Polycystic ovarian syndrome

## Primary outcomes

1

**Description**

Caspase 3 gene expression

**Timepoint**

after 60 days of intervention

**Method of measurement**

real time PCR

2

**Description**

Caspase 7 gene expression

**Timepoint**

after 60 days of intervention

**Method of measurement**

real time PCR

3

**Description**

Survivin gene expression

**Timepoint**

after 60 days of intervention

**Method of measurement**

real time PCR

4

**Description**

serum testosterone

**Timepoint**

before/after intervention (60 days)

**Method of measurement**

elisa

5

**Description**

serum insulin

**Timepoint**

before/after intervention (60 days)

**Method of measurement**

elisa

6

**Description**

serum glucose

**Timepoint**

before/after intervention (60 days)

**Method of measurement**

Enzyme kit

7

**Description**

serum sex hormone binding globulin

**Timepoint**

before/after intervention (60 days)

**Method of measurement**

elisa

8

**Description**

high-density lipoprotein cholesterol

**Timepoint**

before/after intervention (60 days)

**Method of measurement**

Enzyme kit

9

**Description**

serum low-density lipoprotein

**Timepoint**

before/after intervention (60 days)

**Method of measurement**

Enzyme kit

10

**Description**

total cholesterol

**Timepoint**

before/after intervention (60 days)

**Method of measurement**

Enzyme kit

11

**Description**

triglyceride

**Timepoint**

before/after intervention (60 days)

**Method of measurement**

Enzyme kit

## Secondary outcomes

1

**Description**

count and quality of oocyte

**Timepoint**

after 60 days of intervention

**Method of measurement**

counting, optical microscope

2

**Description**

count and quality of embryo

**Timepoint**

48-72 hours after ICSI

**Method of measurement**

counting, optical microscope

3

**Description**

chemical pregnancy

**Timepoint**

14 days after embryo transfer

**Method of measurement**

serum beta HCG test

**4**

**Description**

Clinical pregnancy

**Timepoint**

4 weeks after embryo transfer

**Method of measurement**

ultra-sound

**Intervention groups**

**1**

**Description**

Intervention group: taking a daily dosage of 800mg resveratrol pills ( in 2 capsules of 400mg, one in the morning and one at noon) from mega resveratrol company for 60 days leading to puncture operation date. patients routine drug consumption like metformin is not affected.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: taking a daily dosage of 800mg placebo pills ( in 2 capsules of 400mg, one in the morning and one at noon) for 60 days leading to puncture operation date. patients routine drug consumption like metformin is not affected.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shariati hospital

**Full name of responsible person**

Maryam Shabani Nashtaei

**Street address**

Shariati hospital, Jalal Al Ahmad St., Jalal Al Ahmad Hwy., district 6, Tehran

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+98 21 8490 2413

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maryam.shabani.n@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Nima Rezaei

**Street address**

Tehran university of medical sciences, Pour Sina St., Qods St., Enghelab Blvd, district 6, Tehran

**City**

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**Province**

Tehran

**Postal code**

1461884513

**Phone**

+98 21 8163 3619

**Email**

tums\_edu@tums.ac.ir

**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**

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**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Shabani Nashtaei

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Biology

**Street address**

School of medicine, Tehran university of medical sciences, Poursina St., Qods St., Enghelab Blvd., Tehran

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Tehran

**Province**

Tehran

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maryam.shabani.n@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Maryam Shabani Nashtaei  
**Position**  
assistant professor  
**Latest degree**  
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**Other areas of specialty/work**  
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maryam.shabani.n@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
mohammadhosein bagheri  
**Position**  
MSc student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Anatomy  
**Street address**  
school of medicine, Pour Sina St., Qods St., Enghelab Blvd., tehran.  
**City**

Tehran  
**Province**  
Tehran  
**Postal code**  
1417653761  
**Phone**  
+98 21 6405 3404  
**Email**  
mho3in77@yahoo.com

## 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

Undecided - It is not yet known if there will be 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

june 2024

### 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

Mohammadhosein Bagheri Email :  
mho3in77@yahoo.com phone : +989367542605  
address: Tehran, Enghelab St., Qods St., Poursina, medicine faculty, embryology ward

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

By sending an email to the corresponding author. The applicant can receive the required information within one week if the information is available by specifying the affiliated scientific-educational center.

### Comments