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)

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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 tans-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 placebi 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Nima Rezaei

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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

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Other areas of specialty/work
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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
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