Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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+98 76 3333 0755

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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, Jomhouri 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
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Shahid Mohammadi Hospital, Infertility Center,Shafa Alley, Jomhouri Boulevard
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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, Jomhouri Boulevard
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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
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Person responsible for updating data

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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