Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

The effects of Resveratrol on expression of main ovarian angiogenesis genes (VEGF & HIF-1) & androgene aromatization gene (CYP19) in granolosa cells of PCOS patients and their IVF outcomes.

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 CYP19, VEGF & HIF-1 will quantify by the real-time PCR (SYBR green). Finally, The sexual hormones & Fertility outcomes of the patients (like; oocytes quality, number of oocytes, fertilization rate, cleavage rate, embryos quality, number of embryos & chemical pregnancy rate) will be assessed and compromised in two groups.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016030126860N1**
Registration date: **2016-03-15, 1394/12/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-03-15, 1394/12/25

Registrant information

Name

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Name of organization / entity

Tehran University of Medical Siences

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Recruitment status

Recruitment complete

Funding source

Governmental- Tehran University of Medical Sciences.

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Resveratrol on expression of main ovarian angiogenesis genes (VEGF & HIF-1) & androgene aromatization gene (CYP19) in granolosa cells of PCOS patients and their IVF outcomes.

Public title

The effects of Resveratrol on PCOS.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Infertility with documented PCOS & Hyperandrogenism; 18-40 Y/O; Candidate for IVF Cycle; If have male factor; it must mild to moderate form, not non-obstructive azospermia; If have other female factor; only cervical & tubal factors are acceptable. Exclusion Criteria: FSH>10; Severe endometriosis (Stage III or IV); Coshing Syndrome; Hyperprolactinemia; Thyroid

diseases; Ovarian Tumors; Severe male factor like non-Obstructive Azospermia; Steroids & OCP taking History in past 3 months; SLE (Systemic Lupus Erythematosus) & autoimmune diseases; Systemic diseases like Metabolic Syndrome, Hyperlipidemia, Diabetes & cardiovascular diseases; Diseases due to malnutrition & obesity with unknown cause.

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences ethical committee

Street address
Tehran, Poursina St.

City
Tehran

Postal code

Approval date
2016-01-19, 1394/10/29

Ethics committee reference number
IR.TUMS.REC.1394.1690

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
CYP19 Expression

Timepoint
After follicle retrieval (Approximately 40 days after treatment)

Method of measurement
Real-time relative quantification

2

Description
VEGF Expression

Timepoint
After follicle retrieval (Approximately 40 days after treatment)

Method of measurement
Real-time relative quantification

3

Description
HIF-1 Expression

Timepoint
After follicle retrieval (Approximately 40 days after treatment)

Method of measurement
Real-time relative quantification

4

Description
Sexual hormones (Including; FSH, LH, Estradiol, TSH, Prolactin, Progestrone, Testestrone & AMH)

Timepoint
Before & After Intervention

Method of measurement
By IFA Method

5

Description
Number of retrieved Oocytes

Timepoint
After Intervention

Method of measurement
Count Under Microscope

6

Description
Number of retrieved Mature Oocytes (MII)

Timepoint
After Intervention

Method of measurement
Count Under Microscope

7

Description

Quality of Retrieved Oocytes

Timepoint

After Intervention

Method of measurement

Based on WHO Criteria

8

Description

Number of fertilized eggs

Timepoint

After Intervention

Method of measurement

Based on No. of 2PN oocytes

9

Description

Fertilization rate

Timepoint

After Intervention

Method of measurement

fertilized egg number devided to retrieved oocyte number

10

Description

Number of Cleavage embryos

Timepoint

After Intervention

Method of measurement

Count the Cleavage (8 Cells) embryos

11

Description

Cleavage rate

Timepoint

After Intervention

Method of measurement

embryo number devided to fertilized egg number

12

Description

High Quality Embryo Rate

Timepoint

After Intervention

Method of measurement

Count the Grade 1&2 of embryo quality

13

Description

Chemical Pregnancy Rate

Timepoint

After Intervention

Method of measurement

B-hCG test

14

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, 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

Sarem Women's Hospital

Full name of responsible person

Mrs. Shami

Street address

Phase-3 Shahrak-e-Ekbatan

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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
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

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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