Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The effects of Resveratrol on expression of some ER stress pathway genes in granulosa cells and some circulating inflammatory markers in PCOS patients

Protocol summary

Summary

his 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 ATF4, ATF6, CHOP, GRP78, XBP1 in granulosa cells and expression of the NF-κB in polymorphonuclear cells will quantify by the real-time PCR (SYBR green). Finally, some circulating inflammatory factors (IL-6, IL-18, IL-1beta, TNF-alpha, CRP), insulin resistance factors(glucose, insulin, homosyctein, HOMA-IR, QUICKI), some biochemical factors(LDL, HDL, Trigliseride, cholestrole, FBS) and also ROS(PC & MD) and TAC in serum and follicular fluid will be assessed and compromised in two groups. Fertility outcomes of the patients (like; oocytes quality, number of oocytes, fertilization rate, cleavage rate, embryos quality, number of embryos, chemical and clinical pregnancy rate) will be assessed and compromised in two groups.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016041827453N1**
Registration date: **2016-05-25, 1395/03/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-25, 1395/03/05

Registrant information

Name
Samaneh Brenjian
Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Governmental- Tehran University of Medical Sciences.

Expected recruitment start date

2016-05-04, 1395/02/15

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Resveratrol on expression of some ER stress pathway genes in granulosa cells and some circulating inflammatory markers in PCOS patients

Public title

The effects of Resveratrol on PCOS.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Infertility with documented PCOS based on Rotterdam criteria; 18-40 Y/O; If have male factor; it must be mild to moderate form, not non-obstructive azospermia; If have other female factor; only cervical & tubal factors are acceptable; Candidate for IVF Cycle; No insulin taking history; Not eating red grapes, pistachio, peanut and berries recently. Exclusion Criteria: Diseases due to obesity with unknown cause (Hypothyroidism, Coshing Syndrome); . FSH>10 at third day of the cycle; Severe endometriosis (Stage III or IV); Thyroid diseases; Congenital Adrenal Hyperplasia; Hyperprolactinemia; Ovarian Tumors; Taking Steroids, OCP and other drugs that affect ovarian function, insulin sensitivity or lipid metabolism in past 3 months (except routin PCOS therapy); SLE (Systemic Lupus Erythematosus) & autoimmune diseases; Systemic diseases like Metabolic Syndrome, Hyperlipidemias & cardiovascular diseases; Severe male factor like non-Obstructive Azospermia (sperm concentration < 5 mill/m); Patients who use vitrification method to avoid OHSS; Having alergy to some fruits like red grapes, pistachio and red berry; Insulin taking history

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
-Randomized Controlled Trial

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Tehran, Poursina St.

City
Tehran

Postal code

Approval date
2016-01-27, 1394/11/07

Ethics committee reference number
IR.TUMS.REC.1394.1755

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
ATF4 Expression

Timepoint
After follicle retrieval (Approximately 40 days after treatment)

Method of measurement
Real-time relative quantification

2

Description
ATF6 Expression

Timepoint
After follicle retrieval (Approximately 40 days after treatment)

Method of measurement
Real-time relative quantification

3

Description
CHOP Expression

Timepoint
After follicle retrieval (Approximately 40 days after treatment)

Method of measurement
Real-time relative quantification

4

Description
GRP78 Expression

Timepoint
After follicle retrieval (Approximately 40 days after treatment)

Method of measurement
Real-time relative quantification

5

Description
XBP1 Expression

Timepoint
After follicle retrieval (Approximately 40 days after treatment)
Method of measurement
Real-time relative quantification

6

Description
inflammatory factors(IL-6, IL-18, IL-1beta, TNF-alpha, CRP)
Timepoint
Before & After Intervention
Method of measurement
By ELISA Method

7

Description
Insulin Resistance factors(glucose, insulin, homocystein, QUICKI, HOMA-IR)
Timepoint
Before & After Intervention
Method of measurement
By Espectrophotometry Method

8

Description
Biochemical Factors(FBS, cholestrole, Trigliseride, HDL, LDL)
Timepoint
Before & After Intervention
Method of measurement
By Photometry Method

9

Description
ROS (Reactive Oxygen Species: PC & MD)
Timepoint
After follicle retrieval (Approximately 40 days after treatment) , Before & After Intervention
Method of measurement
By Espectrophotometry Method

10

Description
NF-κB Expression
Timepoint
Before & After Intervention
Method of measurement
Real-time relative quantification

11

Description
TAC (Total Antioxidant Capacity)
Timepoint
After follicle retrieval (Approximately 40 days after treatment) , Before & After Intervention
Method of measurement
By Espectrophotometry Method

12

Description
Number of retrieved Oocytes
Timepoint
After Intervention
Method of measurement
Count Under Microscope

13

Description
Number of retrieved Mature Oocytes (MII)
Timepoint
After Intervention
Method of measurement
Count Under Microscope

14

Description
Quality of Retrieved Oocytes
Timepoint
After Intervention
Method of measurement
Based on WHO Criteria

15

Description
Number of fertilized eggs
Timepoint
After Intervention
Method of measurement
Based on No. of 2PN oocytes

16

Description
Fertilization rate
Timepoint
After Intervention
Method of measurement
fertilized egg number devided to retrieved oocyte number

17

Description
Number of Cleavage embryos
Timepoint
After Intervention
Method of measurement
Count the Cleavage (8 Cells) embryos

18

Description
Cleavage rate
Timepoint
After Intervention
Method of measurement

embryo number devided to fertilized egg number

19

Description
High Quality Embryo Rate
Timepoint
After Intervention
Method of measurement
Count the Grade 1&2 of embryo quality

20

Description
Chemical Pregnancy Rate
Timepoint
After Intervention
Method of measurement
B-hCG test

21

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 (manufactured by Biovita company), 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
Arash Hospital
Full name of responsible person
Street address
Tehranpars second square
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of 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
Vice chancellor for research of 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

Contact
Name of organization / entity
Tehran University of Medical sciences
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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