Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of quercetin on the inflammatory factors NfKb, TnfAlpha, Il6 and expression of the Nrf2 and Keap1 genes in poly cystic ovary syndrome (PCOS Patients)

Protocol summary

Study aim
Help to find a treatment for PCOS patients

Design
All standard treatment for PCOS patients done , the only difference is consumption of Quercetin tablets or placebo

Settings and conduct
Blood samples are taken from patients in the beginning of menstruation(The blood sample is immediately centrifuged and the resulting serum is stored at an appropriate temperature of -20 ° C). Then consuming a dose of 500 mg per day of Quercetin in the intervention group or placebo in the control group will start. After 40 days, on the day of ovulation, the blood sample is taken again. After puncture surgery the granulosa cells are isolated and cultured. Finally by using PCR , the expression of Nrf2 and Keap1 genes in mentioned granulosa cells studied.

Participants/Inclusion and exclusion criteria
In this study, after confirmation of diagnosis (PCOS) in patients based on Rotterdam criteria, candidates for in vitro fertilization (IVF) are admitted to the study by below criterions. Inclusion: -Has an infertility problem -Infection with confirmed PCOS with hyperandrogenism -Age between 20 to 37 years -Mild to moderate male factor -Accompanying female infertility factors are tubal or infertility of unknown origin. Exclusion: -FSH higher than 10 -Hyperprolactinemia, thyroid disease -Receive any ocp, hormonal treatments in the last trimester

Intervention groups
Intervention in the intervention group: administration of quercetin QUR supplement, in the amount of 500 mg daily oral capsules, for 40 days from the first day of the menstrual cycle to the day of follicle recovery. Intervention in the control group: administration of quercetin QUR placebo, in the amount of 500 mg daily capsules, for 40 days from the first day of the menstrual cycle to the day of follicle recovery from patients.

Main outcome variables
Effects on inflamatory factors of TNFalpha, Nfkb, IL6

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210516051323N1**
Registration date: **2021-11-16, 1400/08/25**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-16, 1400/08/25**
Update count: **0**

Registration date
2021-11-16, 1400/08/25

Registrant information

Name
Sima Vaez

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4022 8954

Email address
vaezmrs@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-22, 1400/07/30

Expected recruitment end date
2021-12-21, 1400/09/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of quercetin on the inflammatory factors NfKb, TnfAlpha, Il6 and expression of the Nrf2 and Keap1 genes in poly cystic ovary syndrome (PCOS Patients)

Public title

Effect of Quercetin on PCOS patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertility with documented PCOS & Hyperandrogenism;20-37Y/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:

Age

From **20 years** old to **37 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **42**

More than 1 sample in each individual

Number of samples in each individual: **2**

Two blood sample + one follicular sample

Randomization (investigator's opinion)

Randomized

Randomization description

(Block Randomization) 42 patients are randomly assigned to the intervention and control groups by blocking method, and each for a period of 40 days from the beginning of the menstrual cycle to the day of ovulation, will receive a daily dose of 500 mg of quercetin for the intervention group or a placebo for the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding is done by assigning a number to each patient. Quercetin and placebo capsules are the same. A person who is not involved in the study prepares the containers of both groups by placing quercetin and placebo tablets in the same containers and assigning codes. Both researchers and study participants are blind from the time of randomization to the time of data analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of islamic azad university science and research branch Tehran

Street address

Daneshgah Sq, North end sattari Exw, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1477893855

Approval date

2021-02-14, 1399/11/26

Ethics committee reference number

IR.IAU.SRB.REC.1399.213

Health conditions studied

1

Description of health condition studied

Poly Cystic Ovary Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Inflamatory factors TNfAlpha, IL6

Timepoint

Before consumption and after puncture surgery

Method of measurement

Elaysa Test on blood sample

Secondary outcomes

1

Description

Effects on expression of Nrf2-Keap1 genes

Timepoint

After puncture surgery

Method of measurement

Real Time PCR Device records

2

Description

Protein expression, Keap-1

Timepoint

After the intervention

Method of measurement
western blot

Intervention groups

1

Description
For Intervention Group: quercetin, Orally 500 mg/day (1 Cap.) for 40 days from the beginning of the menstruation cycle till oocyte retrieval.
Category
Placebo

2

Description
Intervention group: Placebo of quercetin, Orally 1 Cap. for 40 days from the beginning of the menstruation cycle till oocyte retrieval.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash Hospital Tehran
Full name of responsible person
Sima Vaez
Street address
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Kazem Parivar
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North sattari , Daneshgah Sq. SRBIAU
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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
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Sima Vaez
Position
Student
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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
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Part of the participants data related to main topic of research
When the data will become available and for how long
6 months after first formal issue
To whom data/document is available
Academic Researchers
Under which criteria data/document could be used
Written Approval
From where data/document is obtainable
Sima Vaez
What processes are involved for a request to access data/document
Submit a request via email
Comments