

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 inflammatory 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

Inflammatory 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

Arash Hosp, Baghdarnia St, Tehranpars

City

Tehran

Province

Tehran

Postal code

1653959469

Phone

+98 21 7788 3283

Email

hosp_arash@tums.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Kazem Parivar

Street address

North sattari , Daneshgah Sq. SRBIAU

City

Teharn

Province

Tehran

Postal code

14778938551

Phone

+98 21 4486 5154

Email

basic-fa@srbiau.ac.ir

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

Latest degree

Master

Other areas of specialty/work

Reproductive Biology

Street address

unit3 no53 pabarja st shariati st Tehran

City

Tehran

Province

Tehran

Postal code

1949635771

Phone

+98 21 4022 8954

Email

vaezmrs@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

kazem parivar

Position

ph.D in Animal Developmental Cell Biology

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

Street address

Tehran, The end of Shahid Sattari Highway, University Square of Shohada Hesarak Boulevard, Islamic Azad University, Science and Research Branch

City

Tehran

Province

Tehran

Postal code

1477893855

Phone

+98 21 4486 5179

Fax**Email**

basic-fa@srbiau.ac.ir

1949635771

Phone

+98 21 4022 8954

Fax**Email**

vaezmrs@gmail.com

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**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Sima Vaez

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

Reproductive Biology

Street address

Shariati St, Pabarja No53 U3

City

Tehran

Province

Tehran

Postal code