Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of supplementation of quercetin on inflammatory factor and adiponectin and gene expression of its receptors in women’s PBMC with polycystic ovary syndrome(PCOS)

Protocol summary

Summary

According to investigations, seems to be the first in the world and Iran the Effect of supplementation of quercetin on inflammatory factor and adiponectin and gene expresion. This clinical trial is designed as a double blind. Individuals who wish to participate in the study,and donot problem with quercetin supplementation include in . Inclusion criteria: BMI 25 to 40 - the age range of 20-40 years - according to the Rotterdam conference, at least two of the three criteria listed as having the disease. Features include menstrual irregularities, or clinical symptoms and the presence of polycystic ovaries on ultrasound – Hyperandrogenism. donot use drugs; contraceptive drugs, antihypertensive drugs lower blood lipid and anti-inflammatory drug- and willing to cooperate. Exclusion criteria: Endocrine and metabolic diseases such as hypothyroidism and hyperthyroidism, androgen producing cancer, diabetes mellitus, adrenal hyperplasia and Cushing, ovarian tumor and Hyperprolactinaemia - Smoking - Pregnancy - allergic reaction to supplements - Cancel patient to cooperate in the study. In this study, 84 women (pcos) and in two groups of 42 patients will be enrolled and quercetin supplementation or placebo for 3 months will receive. Groups receiving 1 g daily quercetin supplementation in the form of two tablets of 500 mg after 2 main meals (breakfast and lunch) .. Blood samples were taken before and after the intervention. Blood cells will be separated at the beginning and end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112515536N1**
Registration date: **2014-05-14, 1393/02/24**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2014-05-14, 1393/02/24

Registrant information

Name

Mohammad Javad Hosseinzadeh

Name of organization / entity

School of Nutritional Sciences and Dietetics, TUMS

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sicences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of supplementation of quercetin on inflammatory factor and adiponectin and gene expression of its receptors in women’s PBMC with polycystic ovary syndrome(PCOS)

Public title

The effect of quercetin on PCOS patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: BMI 25 to 40 - the age range of 20-40 years - according to the Rotterdam conference, at least two of the three criteria listed as having the disease. Features include menstrual irregularities, or clinical symptoms and the presence of polycystic ovaries on ultrasound – Hyperandrogenism. donot use drugs; contraceptive drugs, antihypertensive drugs lower blood lipid and anti-inflammatory drug- and willing to cooperate. Exclusion criteria: Endocrine and metabolic diseases such as hypothyroidism and hyperthyroidism, androgen producing cancer, diabetes mellitus, adrenal hyperplasia and Cushing, ovarian tumor and Hyperprolactinaemia - Smoking - Pregnancy - allergic reaction to supplements - Cancel patient to cooperate in the study.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Sixth Floor-Central Tehran University-Qods St., Keshavarz Blvd-tehran

City

Tehran

Postal code

Approval date

2014-02-15, 1392/11/26

Ethics committee reference number

104428

Health conditions studied

1

Description of health condition studied

Polycystic Ovary Syndrome

ICD-10 code

E28.2

ICD-10 code description

Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes

1

Description

Serum adiponectin

Timepoint

Before and after intervention

Method of measurement

Adiponectin ELISA Kit µg / ml

Secondary outcomes

1

Description

Tumor necrosis factor

Timepoint

Before and after intervention

Method of measurement

Serum concentrations of TNFα ELISA kit

2

Description

C-reactive protein

Timepoint

Before and after intervention

Method of measurement

Serum levels of hs-CRP ELISA Kit

3

Description

high-molecular weight adiponectin levels

Timepoint

Before and after intervention

Method of measurement

Adiponectin ELISA Kit µg / ml

4

Description

Glucose

Timepoint

Before and after intervention

Method of measurement

Serum ELISA Kit

5

Description
Insulin
Timepoint
Before and after intervention
Method of measurement
Serum ELISA kit micro mol / l

6

Description
adenosine monophosphate-activated protein kinase
Timepoint
Before and after intervention
Method of measurement
Serum ELISA Kit

7

Description
Adiponectin receptor 1
Timepoint
Before and after intervention
Method of measurement
RT-PCR

8

Description
Adiponectin receptor 2
Timepoint
Before and after intervention
Method of measurement
RT-PCR

9

Description
Testosterone
Timepoint
Before and after intervention
Method of measurement
Serum Elisa kit

10

Description
Progesterone
Timepoint
Before and after intervention
Method of measurement
serum Elisa kit

11

Description
Luteinizing hormone
Timepoint
Before and after intervention
Method of measurement
ELISA kit

12

Description
follicle stimulating hormone
Timepoint
Before and after intervention
Method of measurement
ELISA kit

13

Description
Sex Hormone Binding Globulin
Timepoint
Before and after intervention
Method of measurement
IRMA

14

Description
systolic blood pressure
Timepoint
Before and after intervention
Method of measurement
Pressure set

15

Description
diastolic blood pressure
Timepoint
Before and after intervention
Method of measurement
Pressure set

16

Description
Total cholesterol
Timepoint
Before and after intervention
Method of measurement
Serum total cholesterol concentration turbidometry mg / dl

17

Description
Triglyceride
Timepoint
Before and after intervention
Method of measurement
Serum triglyceride concentrations were enzymatically mg / dl

18

Description
Low-density lipoprotein
Timepoint
Before and after intervention
Method of measurement
LDL-C levels

19

Description
High-density lipoprotein
Timepoint
Before and after intervention
Method of measurement
Serum HDL cholesterol concentration

Intervention groups

1

Description
to the intervention group Quercetin supplements , 1 g daily for 12 weeks as the two tablets of 500 mg after 2 main meals (breakfast and lunch)and should not be taken on an empty stomach.
Category
Treatment - Drugs

2

Description
Patients in the placebo group will receive 12 weeks of placebo quercetin
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr mohammad reza Hadian
Street address
International Campus-tehran university of medical science-porsina ave-ghods street-keshavarz blv-tehran
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
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

2

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Masoud Younesian
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Sixth Floor-Central University,Qods St., Keshavarz Blvd,tehran
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
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