

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Quercetin supplementation on plasma level of Resistin and its gene expression in Peripheral blood mononuclear cells and metabolic risk factors in women with Polycystic ovary syndrome.

Protocol summary

Summary

The main objective of this study was to determine the effect of Quercetin supplementation on plasma Resistin levels and gene expression in Peripheral blood mononuclear cells and metabolic risk factors in women with Polycystic ovary syndrome. This study is a Double-blind, placebo-controlled randomized clinical trial. Sample size for this study is 76 person base on the power of 90 percent. Ask patients be present in the hospital on certain day while 12 to14 hour fast. After explaining the purpose and methodology of the study and obtaining informed consent from patients, 10 Milliliter fasting venous blood samples are taken and then measure the height and weight of patients. Participants should not have endocrine and metabolic disease like Hypothyroidism and Hyperthyroidism, Diabetes Mellitus, Adrenal Hyperplasia, Cushing, Hyperprolactinemia, Ovarian tumor and do not eat any drug that impact on our results for example Metformin and lowering blood fat and weight-loss drugs. Patients in the group taking the supplement quercetin, receive 1 Gram supplement after breakfast and lunch in the form of two tablets of 500 mg for 12weeks duration. Patients in the placebo group receive quercetin placebo for 12 weeks, with similar recommendations. At the beginning and end of the intervention, lipid levels, blood glucose, insulin, serum resistin concentrations and inflammatory factors such as Tumor necrosis factor alpha will be measured and the information will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082215536N4**

Registration date: **2017-03-04, 1395/12/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-04, 1395/12/14

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

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

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 effect of Quercetin supplementation on plasma level of Resistin and its gene expression in Peripheral blood mononuclear cells and metabolic risk factors in women with Polycystic ovary syndrome.

Public title

Effect of Quercetin supplementation on women with Polycystic ovary syndrome.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: people with Body Mass Index between 25 to 40; age range of 20 to 40 year; According to the Rotterdam conference have at least 2 of the 3 criteria listed index as the disease is consider; criteria include irregular periods clinical or biochemical Hyperandrogenism and existence of Polycystic ovary base on ultrasound; willingness to cooperate; lack of medication Metformin; Oral contraceptive pill; Antihypertensive drug; lowering blood fat; Anti-inflammatory; Weight-loss drugs. Exclusion criteria: suffering from endocrine and metabolic disease like Hypothyroidism and Hyperthyroidism; Cancer androgen manufacturer; Diabetes mellitus; Adrenal Hyperplasia; Cushing; Ovarian tumors; Hyperprolactinemia; Smoking; Pregnancy; Lactation; Menopause; allergic reaction to the supplement; withdrew the patient from the study cooperation

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

For randomization, Quad blocks (21 blocks) generate by Excel software and the process of getting patients into groups base on these blocks are set.

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**

2017-01-02, 1395/10/13

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1378

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**

Plasma Resistin

Timepoint

Before and after intervention

Method of measurement

Resitin ELISA Kit

Secondary outcomes**1****Description**

C-reactive protein

Timepoint

Before and after intervention

Method of measurement

Serum levels of hs-CRP ELISA Kit

2**Description**

Glucose

Timepoint

Before and after intervention

Method of measurement

Serum ELISA Kit

3**Description**

Insulin

Timepoint

Before and after intervention

Method of measurement

Serum ELISA kit micro

4

Description

Testosterone

Timepoint

Before and after intervention

Method of measurement

Serum Elisa kit

5

Description

Progesterone

Timepoint

Before and after intervention

Method of measurement

serum Elisa kit

6

Description

Luteinizing hormone

Timepoint

Before and after intervention

Method of measurement

ELISA kit

7

Description

Follicle-stimulating hormone

Timepoint

Before and after intervention

Method of measurement

ELISA kit

8

Description

Sex Hormone Binding Globulin

Timepoint

Before and after intervention

Method of measurement

IRMA

9

Description

Systolic blood pressure

Timepoint

Before and after intervention

Method of measurement

Pressure set

10

Description

Diastolic blood pressure

Timepoint

Before and after intervention

Method of measurement

Pressure set

11

Description

Resistin level

Timepoint

Before and after intervention

Method of measurement

RT-PCR

12

Description

Total cholesterol

Timepoint

Before and after intervention

Method of measurement

Serum total cholesterol concentration turbidometry

13

Description

Triglyceride

Timepoint

Before and after intervention

Method of measurement

Serum triglyceride concentrations were enzymatically

14

Description

Low-density lipoprotein

Timepoint

Before and after intervention

Method of measurement

LDL-C levels

15

Description

High-density lipoprotein

Timepoint

Before and after intervention

Method of measurement

Serum HDL cholesterol concentration

Intervention groups

1

Description

Intervention group; receive Quercetin supplements 1 Gram daily for 12 weeks as the two tablets of 500 Milligram after 2 main meals (breakfast and lunch) and this supplement should not be taken on an empty stomach.

Category

Treatment - Drugs

2

Description

Placebo group: receive placebo Quercetin for 12 weeks daily

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Hospital

Full name of responsible person

Dr. Ashraf Moini

Street address

West 162nd Street, Resalat highway, Tehran

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. 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

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

Full name of responsible person

Masoud Khorshidi

Position

MSc Student Nutrition

Other areas of specialty/work

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City

Tehran

Postal code

Phone

00

Fax

Email

Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty