Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of the effect of coenzyme Q10 supplementation compared with the placebo on gene expression related to inflammation and lipid in patients with polycystic ovary syndrome

Protocol summary

Summary

Objective: The aim of this study is to determine the effects of Q10 supplementation on gene expression related to inflammation and lipid in patients with polycystic ovary syndrome. Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers. Inclusion criteria: Patients with polycystic ovary syndrome and aged 18 to 40 years will be included in this study. Exclusion criteria: Unwillingness to cooperate will be excluded in the study. Population and sample size: 40 patients with polycystic ovary syndrome of eligible and referred to Persian Gulf Martyrs Hospital affiliated to Bushehr University of Medical Sciences, Bushehr, Iran in the study will be selected. Intervention: Patients will be assigned to receive either Q10 (n=20) or placebo (n=20). Q10 and placebos capsules are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and end of the intervention: 12 weeks. Outcomes: Gene expression related to inflammation (primary outcomes) and lipid (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612315623N97**
Registration date: **2017-01-02, 1395/10/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-01-02, 1395/10/13

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical Sciences

Expected recruitment start date

2016-11-15, 1395/08/25

Expected recruitment end date

2016-12-05, 1395/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of coenzyme Q10 supplementation compared with the placebo on gene expression related to inflammation and lipid in patients with polycystic ovary syndrome

Public title

Effect of supplementation in treatment of patients with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with polycystic ovary syndrome; aged 18 to 40 years. Exclusion criteria: Unwillingness to cooperate.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Random assignment will be done by the use of computer-generated random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Bushehr University of Medical Sciences

Street address

Bahmani Campus, Bushehr University of Medical Sciences, Sabzabad Blvd

City

Bushehr

Postal code

Approval date

2016-11-14, 1395/08/24

Ethics committee reference number

IR.BPUMS.REC.1395.105

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovary syndrome

Primary outcomes

1

Description

TNF-α

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

PCR-RT

2

Description

IL-1

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

PCR-RT

Secondary outcomes

1

Description

Ox-LDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

PCR-RT

Intervention groups

1

Description

Intervention group: 100 mg coenzyme Q10 (Nature, New York, USA), once a day, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Barij Essence, Kashan, Iran), once a day, for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Persian Gulf Martyrs Hospital

Full name of responsible person

Dr Elham Rahmani

Street address

Persian Gulf Martyrs Hospital, Borj square, Borj Blvd

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research, Bushehr University of Medical Sciences

Full name of responsible person

Dr Afshin Ostovar

Street address

Bahmani Campus, University of Medical Sciences, Sabzabad Blvd

City

Bushehr

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor of research, Bushehr 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Other areas of specialty/work

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Web page address

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