

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 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 placebo 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)

##### Phone

+98 36 1534 3570

##### Email address

asemi\_z@kaums.ac.ir

#### 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- $\alpha$

#### **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

##### Street address

Ghotbe Ravandi Boulevard, Kashan

##### City

Kashan

##### Postal code

##### Phone

+98 31 5546 3378

##### Fax

##### Email

asemi\_z@kaums.ac.ir; asemi\_r@yahoo.com

##### Web page address

## Person responsible for updating data

#### 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

##### Street address

Ghotbe Ravandi Boulevard, Kashan

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Kashan

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##### Fax

##### Email

asemi\_z@kaums.ac.ir; asemi\_r@yahoo.com

##### 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*