

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of Q10 supplementation on metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome candidates for IVF

#### Protocol summary

##### Study aim

Objective: The aim of this study is to determine the effects of Q10 supplementation on metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome candidates for IVF

##### Design

Study design: Randomized double-blind placebo-controlled trial, All participants will have stratified randomization according to BMI (<25 and  $\geq$ 25 kg/m<sup>2</sup>) and age (<30 and  $\geq$ 30 y). Then, participants in each block will be randomly allocated into two groups. Randomization will be done by the use of computer software.

##### Settings and conduct

Among patients with polycystic ovary syndrome candidates for IVF referred to Kosar Clinic affiliated to Arak University of Medical Sciences, 40 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 8 weeks after the intervention. At the beginning and the end of the intervention: 8 weeks

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with polycystic ovary syndrome candidates for IVF aged 18 to 40 years.  
Exclusion criteria: Individuals with neoplastic disorders, cardiovascular diseases, malabsorptive disorders, and current or previous (within the last 6 months) use of hormonal; antidiabetic and anti-obesity medications.

##### Intervention groups

Intervention group: 100 mg Q10 (Pharmed-Tnt Inc, Canada), once a day, for 8 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), once a day, for 8 weeks orally.

##### Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profiles and gene expression related to insulin and lipid (secondary outcomes) will be quantified at study baseline and end-of-trial.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170513033941N52**

Registration date: **2019-03-28, 1398/01/08**

Registration timing: **retrospective**

Last update: **2019-03-28, 1398/01/08**

Update count: **0**

##### Registration date

2019-03-28, 1398/01/08

##### Registrant information

##### Name

Mohammadreza Sharif

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5546 3378

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ostadmohammadi-vr@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-17, 1397/09/26

##### Expected recruitment end date

2019-01-16, 1397/10/26

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
The effect of Q10 supplementation on metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome candidates for IVF

**Public title**  
The effect of Q10 supplementation in treatment of women with polycystic ovary syndrome

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with polycystic ovary syndrome candidates for IVF Individuals aged 18 to 40 years

**Exclusion criteria:**

Individuals with neoplastic disorders cardiovascular diseases malabsorptive disorders current or previous (within the last 6 months) use of hormonal; antidiabetic and anti-obesity medications.

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m<sup>2</sup>) and age (<30 and ≥30 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Shabihkhani clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

**Street address**

Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue,

**City**

Arak

**Province**

Markazi

**Postal code**

1771844351

**Approval date**

2018-12-16, 1397/09/25

**Ethics committee reference number**

IR.ARAKMU.REC.1397.245

**Health conditions studied**

1

**Description of health condition studied**

Polycystic ovary syndrome

**ICD-10 code**

E28.2

**ICD-10 code description**

Polycystic ovarian syndrome

**Primary outcomes**

1

**Description**

Insulin resistance

**Timepoint**

At the beginning of the study and after 8 weeks of intervention

**Method of measurement**

Calculation using HOMA formula

2

**Description**

Insulin

**Timepoint**

At the beginning of the study and after 8 weeks of intervention

**Method of measurement**

Elisa kit

## Secondary outcomes

### 1

#### Description

Total cholesterol

#### Timepoint

At the beginning of the study and after 8 weeks of intervention

#### Method of measurement

Enzymatic kit

### 2

#### Description

HDL

#### Timepoint

At the beginning of the study and after 8 weeks of intervention

#### Method of measurement

Enzymatic kit

### 3

#### Description

Triglycerides

#### Timepoint

At the beginning of the study and after 8 weeks of intervention

#### Method of measurement

Enzymatic kit

### 4

#### Description

Expressed levels of GLUT-1 gene

#### Timepoint

At the beginning of the study and after 8 weeks of intervention

#### Method of measurement

PCR

### 5

#### Description

Expressed levels of LDL-R gene

#### Timepoint

At the beginning of the study and after 8 weeks of intervention

#### Method of measurement

PCR

## Intervention groups

### 1

#### Description

Intervention group: 100 mg Q10 (Pharmed-Tnt Inc, Canada), once a day, for 8 weeks orally

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo (Barij Essence, Kashan, Iran), once a day, for 8 weeks orally.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kosar Clinic

##### Full name of responsible person

Mehri Jamilian

##### Street address

Emam Khomeyni Avenue, Arak

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Arak

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+98 31 5546 3378

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jamilian\_m@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Mohammad Arjomandzadegan

##### Street address

Vice chancellor for research, Arak University of Medical Sciences

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Arjomandzadegan.M@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Arak University of Medical Sciences

#### 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

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## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Zatollah Asemi  
**Position**  
PhD of Nutrition  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available