

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Clinical trial of the effect of Q10 supplementation compared with the placebo on metabolic profiles in women with polycystic ovary syndrome

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of Q10 supplementation on metabolic profiles in patients with polycystic ovary syndrome

Design

Study design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive Q10 supplements (n=30) or placebo (n=30).

Settings and conduct

Among patients with polycystic ovary syndrome referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, 60 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 12 weeks after the intervention. At the beginning and the end of the intervention: 12 weeks.

Participants/Inclusion and exclusion criteria

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

Intervention groups

Intervention group: 100 mg Q10 (Nature, New York, USA), once a day, for 12 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), once a day, for 12 weeks orally.

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profile (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N21**

Registration date: **2017-12-15, 1396/09/24**

Registration timing: **retrospective**

Last update: **2017-12-15, 1396/09/24**

Update count: **0**

Registration date

2017-12-15, 1396/09/24

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

Email address

ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-29, 1395/07/08

Expected recruitment end date

2016-10-13, 1395/07/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of Q10 supplementation compared with the placebo on metabolic profiles in women with polycystic ovary syndrome

Public title

Effect of Q10 supplementation in treatment of women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: Patients with polycystic ovary syndrome aged 18 to 40 years.

Exclusion criteria:

Exclusion criteria: Unwillingness to cooperate.

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Approval date

2016-09-28, 1395/07/07

Ethics committee reference number

IR.KAUMS.REC.1395.50

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

Timepoint

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

Method of measurement

Elisa kit

2

Description

Insulin resistance

Timepoint

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

Method of measurement

Calculation using HOMA formula

Secondary outcomes

1

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

2

Description

HDL

Timepoint

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

Method of measurement

Enzymatic kit

3

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

4**Description**

FPG

Timepoint

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

Method of measurement

Enzymatic kit

Intervention groups**1****Description**

Intervention group: 100 mg 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**

Naghavi Clinic

Full name of responsible person

Mansoreh Samimi

Street address

Shahid Rajaei Avenue, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 4446 0180

Email

samimi_m@kaums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 5554 2999

Email

hamidi_gh@kaums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kashan 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

Person responsible for general inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Nutritionist

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 5546 3378

Fax**Email**

asemi_z@kaums.ac.ir

Web page address**Person responsible for scientific**

inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Nutritionist

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 5546 3378

Fax

Email

asemi_z@kaums.ac.ir

Web page address

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 5546 3378

Fax

Email

asemi_z@kaums.ac.ir

Web page address

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

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Nutritionist

Latest degree

Ph.D.