Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial of the effect of Q10 supplementation compared with the placebo on hormonal profiles, inflammatory factors and oxidative stress biomarkers 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 hormonal profiles, inflammatory factors and oxidative stress biomarkers 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 supplement (n=30) or placebo (n=30).

Settings and conduct

Among patients with polycystic ovary syndrome referred to Akbarabadi Clinic affiliated to Iran 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: Total testosterone and hs-CRP (primary outcome) and biomarkers of oxidative stress and mental health parameters (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N36**
Registration date: **2018-06-25, 1397/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-25, 1397/04/04**
Update count: **0**

Registration date

2018-06-25, 1397/04/04

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 5546 3378

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ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-14, 1397/03/24

Expected recruitment end date

2018-07-01, 1397/04/10

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 hormonal profiles, inflammatory factors and oxidative stress biomarkers 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. Individuals 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

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to receive supplement or placebo. 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 Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Hemmat Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2018-06-13, 1397/03/23

Ethics committee reference number
IR.IUMS.FMD.REC.1396.9411290014

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
Total testosterone

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

Method of measurement
Elisa kit

2

Description
Hs-CRP

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

Method of measurement
Elisa kit

Secondary outcomes

1

Description
SHBG

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

Method of measurement
Elisa kit

2

Description
Malondialdehyde

Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

3

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

4

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

5

Description
Beck Depression Inventory
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

6

Description
General Health Questionnaire
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

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
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbarabadi Clinic
Full name of responsible person
Dr. Maryam Karamali
Street address
Akbarabadi Hospital, Mowlavi Street, Tehran
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Province
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1168743514
Phone
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Email
karamali.maryam2@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed Kazem Malakouti
Street address
Vice chancellor for research, Iran University of Medical Sciences, Hemmat Highway, Tehran
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kmalakouti@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
PhD of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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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