Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Clinical trial of the effect of Q10 supplementation compared with the placebo on levels of gene expression related with glycemic control and inflammatory factors in women with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study is to determine the effects of Q10 supplementation on levels of gene expression related with glycemic control and inflammatory factors, and metabolic profiles in patients with polycystic ovary syndrome.

Design

Parallel double-blind (both patients and researchers) clinical trial

Settings and conduct

Among patients with polycystic ovary syndrome referred to Kosar Clinic affiliated to Arak University of Medical Sciences and Persian Gulf Martyrs Hospital affiliated to Bushehr University of Medical Sciences, 60 patients (for metabolic profiles and 40 patients for gene expression) will be selected according to inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Patients with polycystic ovary syndrome aged 18 to 40 years will be included in this study. Exclusion criteria will as follows: Pregnant women, adrenal hyperplasia, androgen-secreting tumors, hyperprolactinaemia, thyroid dysfunction, diabetes or impaired glucose tolerance, gastrointestinal problems, no hormonal treatments in the previous 6 months in the study.

Intervention groups

Patients will be assigned to receive either Q10 (n=30) or placebo (n=30) for metabolic profiles, and to receive either Q10 (n=20) or placebo (n=20) for gene expression.

Main outcome variables

Levels of gene expression related with glycemic control and insulin metabolism (primary outcomes), and gene expression related to inflammatory factors and lipid profiles (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Due to an error, the request for an update in our website has conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201605225623N80**
Registration date: **2016-06-04, 1395/03/15**
Registration timing: **retrospective**

Last update: **2020-08-26, 1399/06/05**
Update count: **1**

Registration date

2016-06-04, 1395/03/15

Registrant information

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Zatollah Asemi
Name of organization / entity
Kashan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2016-04-25, 1395/02/06

Expected recruitment end date
2016-05-05, 1395/02/16
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 levels of gene expression related with glycemic control and inflammatory factors in women with polycystic ovary syndrome

Public title
Effect of supplementation in treatment of women with polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with PCOS according to Rotterdam criteria Aged 18 to 40 years
Exclusion criteria:
Pregnant women Adrenal hyperplasia Androgen-secreting tumors Hyperprolactinaemia Thyroid dysfunction Diabetes or impaired glucose tolerance Gastrointestinal problems No hormonal treatments in the previous 6 months in the study
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
Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 60 by a random number generator (https://stattrek.com/statistics/random-number-generator.aspx) and patients will be randomly assigned into each intervention group by their numbers.
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 Clinic who is not involved in the trial and not aware of random sequences will be allocated the numbered bottles of capsules to participants. Supplements and placebo are in the same packaging at the pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of drug and after analyzing the data, packet codes are decoded.
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, Arak
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2016-04-24, 1395/02/05
Ethics committee reference number
IR.ARAKMU.REC.1395.35

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
Expressed levels of PPAR-γ
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

2

Description
Expressed levels of GLUT1 gene

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

3

Description
Serum insulin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Eliza

4

Description
Insulin resistance
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Calculation with HOMA formula

Secondary outcomes

1

Description
Expressed levels of TNFα gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

2

Description
Expressed levels of TGFB gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

3

Description
Expressed levels of IL-1 gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

4

Description
Expressed levels of IL-8 gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

5

Description
Expressed levels of LDLR gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

6

Description
Expressed levels of Lp(a) gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

7

Description
Fasting plasma glucose
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

8

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

9

Description
VLDL-cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

10

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement

Enzymatic kit

11

Description
LDL-cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

12

Description
HDL-cholesterol
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
Kosar Clinic
Full name of responsible person
Mehri Jamilian
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Emam Khomeyni Avenue, Arak
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2

Recruitment center
Name of recruitment center
Persian Gulf Martyrs Hospital
Full name of responsible person
Dr Elham Rahmani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
Mohammad Rafiee
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Arak University of Medical Sciences
Proportion provided by this source
33
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

2

Sponsor
Name of organization / entity
Vice chancellor of research, Bushehr University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice chancellor of research, Bushehr University of Medical Sciences
Proportion provided by this source
33
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

3

Sponsor
Name of organization / entity
Vice chancellor of research, Kashan University of Medical Sciences
Full name of responsible person
Dr Gholamali Hamidi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice chancellor of research, Kashan University of Medical Sciences
Proportion provided by this source
34
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
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PhD of Nutrition
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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable