Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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 ≥25 kg/m2) and age (<30 and ≥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/m2) 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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1771844351
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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
City
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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

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

Nutrition

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Contact

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Full name of responsible person

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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