Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial of the effect of vitamin D supplementation compared with the placebo on gene expression related to insulin, inflammation and lipid in patients with polycystic ovary syndrome

Protocol summary

Summary

Objective: The aim of this study is to determine the effects of vitamin D supplementation on gene expression related to insulin, inflammation and lipid in patients with polycystic ovary syndrome. Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers. Inclusion criteria: Patients with polycystic ovary syndrome and aged 18 to 40 years will be included in this study. Exclusion criteria: Unwillingness to cooperate. Population and sample size: 40 eligible patients with polycystic ovary syndrome who will be referred to Akbarabadi Hospital affiliated to Iran University of Medical Sciences, Tehran, Iran will enroll in the study. Intervention: Patients in intervention group will receive vitamin D (n=20) and patients in the control group will receive placebo (n=20). Vitamin D and placebo capsules are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. Duration of the study: 12 weeks. Outcomes: Gene expression related to insulin (primary outcomes), and inflammation and lipid (secondary outcome) will be quantified at baseline and at the end of the trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701025623N99**
Registration date: **2017-01-06, 1395/10/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-06, 1395/10/17

Registrant information

Name
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, Iran University of Medical Sciences

Expected recruitment start date

2016-12-12, 1395/09/22

Expected recruitment end date

2017-01-11, 1395/10/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of vitamin D supplementation compared with the placebo on gene expression related to insulin, inflammation and lipid in patients with polycystic ovary syndrome

Public title

Effect of supplementation in treatment of patients with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patients with polycystic ovary syndrome; aged 18 to 40 years. Exclusion criteria: Unwillingness to cooperate.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Random assignment will be done by the use of computer-generated random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Vice chancellor for research, Iran University of Medical Sciences, Hemmat Highway, Tehran
City
Tehran
Postal code
Approval date
2016-12-11, 1395/09/21
Ethics committee reference number
IR.IUMS.REC.1395.95-03-30-29748

Health conditions studied

1

Description of health condition studied
Polycystic ovarian 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 12 weeks after intervention
Method of measurement
PCR

2

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

Secondary outcomes

1

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

2

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

3

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

4

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

Intervention groups

1

Description
Intervention group: 50000 IU vitamin D (Zahravi, Tabriz, Iran), once every 2 weeks, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran), once every 2 weeks, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbarabadi Clinic
Full name of responsible person
Maryam Karamali
Street address
Akbarabadi Hospital, Mowlavi Street, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Seyed Ali Javad Moosavi
Street address
Vice chancellor for research, Iran University of Medical Sciences, Hemmat Highway, Tehran
City
Tehran
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, Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
PhD of Nutrition
Other areas of specialty/work
Street address
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Web page address

Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
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Email
asemi_z@kaums.ac.ir; asemi_r@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty