

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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- α 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

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Name of organization / entity

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Full name of responsible person

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Position

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Email

asemi_z@kaums.ac.ir; asemei_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