Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Clinical trial of the effect of vitamin D supplementation compared with the placebo on metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome candidate for IVF

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of vitamin D supplementation on metabolic profiles and gene expression related to insulin and lipid in patients with polycystic ovary syndrome candidate for IVF.

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 vitamin D supplements (n=20) or placebo (n=20).

Settings and conduct

Among patients with polycystic ovary syndrome candidate for IVF referred to Naghavi Clinic affiliated to Kashan 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 candidate for IVF aged 18 to 40 years. Exclusion criteria: Thyroid disorder, diabetes or impaired glucose tolerance.

Intervention groups

Intervention group: 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 8 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran) every 2 weeks, 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: **IRCT20170513033941N27**
Registration date: **2018-01-15, 1396/10/25**
Registration timing: **retrospective**

Last update: **2019-09-15, 1398/06/24**
Update count: **1**

Registration date

2018-01-15, 1396/10/25

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

Email address

ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-26, 1396/10/05

Expected recruitment end date

2018-01-10, 1396/10/20

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 metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome candidate for IVF

Public title
Effect of vitamin D supplementation in treatment of patients with polycystic ovary syndrome candidate for IVF

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: Patients with polycystic ovary syndrome. Individuals aged 18 to 40 years.
Exclusion criteria:
Thyroid disorder Diabetes or impaired glucose tolerance

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
At study baseline, after balanced randomisation, subjects will be allocated 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 Kashan University of Medical Sciences
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159

Approval date
2017-12-25, 1396/10/04

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1396.88

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

Timepoint
At the beginning of the study and after 8 weeks of intervention

Method of measurement
Elisa kit

2

Description
Insulin resistance

Timepoint
At the beginning of the study and after 8 weeks of intervention

Method of measurement
Calculation using HOMA formula

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 PPAR-γ gene
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
PCR

5

Description
Expressed levels of GLUT-1 gene
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
PCR

6

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: 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 8 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran) every 2 weeks, for 8 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi Clinic
Full name of responsible person
Dr. Foroozanfard
Street address
Shahid Rajaee Avenue, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
Email
forozanfar_f@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
Email
hamidi_gh@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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

Nutritionist

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8115187159

Phone

+98 31 5546 3378

Fax

Email

asemi_z@kaums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Nutritionist

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8115187159

Phone

+98 31 5546 3378

Fax

Email

asemi_z@kaums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Nutritionist

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8115187159

Phone

+98 31 5546 3378

Fax

Email

asemi_z@kaums.ac.ir

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