

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The effect of vitamin D supplementation on anthropometric indices and androgen hormones in women with polycystic ovary syndrome treated with low calorie diet

Protocol summary

Summary

objective: The aim of this study is to determine the effects of vitamin D supplementation on anthropometric indices and androgen hormones in women with polycystic ovary syndrome treated with low calorie diet. Study design: Parallel double-blind(both patients and researchers) randomized controlled clinical trial. In this study 60 overweight and obese polycystic ovary syndrome women with vitamin D deficiency referred to Izady hospital in Qom city will be selected. Patients will be assigned into two groups to receive vitamin D with dosage of 50000 IU/week (n=30) or placebo (n=30). Patients in Both groups will be received low calorie diet (An average of 500 kcal). Vitamin D supplements and placebos pill are similar in shape and size. Patients were advised to continue physical activity habits without any changes during intervention. Before intervention and after 12 weeks participants will be evaluated for anthropometric indices, body composition analysis and androgenic profile.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062710826N19**

Registration date: **2016-12-08, 1395/09/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-08, 1395/09/18

Registrant information

Name

Azadeh Nadjarzadeh

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation on anthropometric indices and androgen hormones in women with polycystic ovary syndrome treated with low calorie diet

Public title

effect of Supplementation in combination with diet therapy in treatment of polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged 18-40 years old, Patients with PCOS according to Rotterdam criteria, BMI between 25 to 40, Serum vitamin D levels less than 20 ng /ml, not using

weight loss diet and vitamin D supplement Over the last 3 months, not using hormone therapy, not using certain drugs including Weight loss drugs and multivitamin supplements mineral, not smoking, not doing heavy and professional exercise. Exclusion criteria: individuals with diabetes, Cardiovascular disease, Liver, kidney, thyroid and para- thyroid, Cushing's syndrome, osteomalacia, changes in physical activity, Non-compliance with diet and supplementation

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Randomization 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 Shahid Sadoughi University of Medical Sciences Yazd

Street address

Shahid Sadoughi University of Medical Sciences, alem square

City

Yazd

Postal code

8915173160

Approval date

2016-02-16, 1394/11/27

Ethics committee reference number

IR.SSU.SPH.REC.1394.101

Health conditions studied**1****Description of health condition studied**

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Sclerocystic ovary syndrome, Stein-Leventhal syndrome

Primary outcomes**1****Description**

DHEA (Dehydroepiandrosterone sulfate)

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Elisa method

2**Description**

Total testosterone

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Elisa method

3**Description**

SHBG (sex hormone-binding globulin)

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Elisa method

4**Description**

percent of body fat, percent of free fat mass

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Body composition device

Secondary outcomes**1****Description**

Free androgen index

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Total testosterone/ SHBG

2**Description**

Weight

Timepoint

Before intervention and 12 weeks after intervention
Method of measurement
OMRON scale with an accuracy of 0.1kg

3

Description
Body Mass Index
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
weight/ height*height

4

Description
Waist circumference
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
By meter in cm

5

Description
Hip circumference
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
By meter in cm

6

Description
25OHD (25-hydroxy vitamin D)
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Elisa method

Intervention groups

1

Description
Intervention group: Vitamin D supplements, 50000 IU, weekly, for 12 weeks orally.
Category
Treatment - Other

2

Description
Control group: Placebo, weekly for 12 weeks orally
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center

izadi hospital
Full name of responsible person
samira jafari
Street address
alley 12, golestan avenue, amin boulevard
City
Qom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research.Sahid Sadoughi University of Medical Sciences Yazd
Full name of responsible person
Dr amirhoushang mehrparvar
Street address
Shahid Sadoughi University of Medical Sciences,alem square
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Yazd
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.Sahid Sadoughi University of Medical Sciences Yazd
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
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
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Position
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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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PhD in Nutrition

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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