Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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)

Phone

+98 912 202 2817

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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

City

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

samira jafari sfidvajani

Position

MSc student of Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

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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