

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

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

Protocol summary

Study aim

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

Design

In this study, 40 patients were chosen who have inclusion criteria. participant were randomly allocated to two intervention and placebo groups and given code to each of theme.

Settings and conduct

A randomized double-blind clinical trial was conducted in women with polycystic ovary syndrome and vitamin D deficiency who referred to Izadi Gynaecology clinic of Qom.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The desire to participate in the study, aged 18-40 years, 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 or vitamin D supplement over the last 3 months, not using hormone therapy, not using certain drugs including weight loss drugs or multivitamin supplements mineral, not smoking, not doing heavy and professional exercise. Exclusion criteria: individuals with diabetes, Cardiovascular disease, Liver, kidney, thyroid and parathyroid, Cushing's syndrome, osteomalacia, changes in physical activity, Non-compliance with diet and supplementation.

Intervention groups

Forty women with polycystic ovary syndrome and vitamin D deficiency randomly assigned to intervention (20 participants) and control (20 participants) groups. Participants in intervention group received low-calorie diet + 50,000 IU/week oral vitamin D3 and participants in control group received low-calorie diet + placebo/week (including paraffin) for 12 weeks.

Main outcome variables

Serum 25(OH)D, leptin serum level, weight, Body Mass Index, waist circumference, hip circumference, percent of body fat, percent of free fat mass

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120913010826N30**
Registration date: **2018-07-31, 1397/05/09**
Registration timing: **retrospective**

Last update: **2018-07-31, 1397/05/09**

Update count: **0**

Registration date

2018-07-31, 1397/05/09

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

Email address

azadnajarzadeh@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-22, 1396/05/31

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

2017-09-26, 1396/07/04

Actual recruitment end date

2018-07-05, 1397/04/14

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation on anthropometric indices and Leptin serum level 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 _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 _Patients with PCOS according to Rotterdam criteria _not doing heavy and professional exercise

Exclusion criteria:

individuals with diabetes, Cardiovascular disease, Liver, kidney, thyroid and para- thyroid, Cushing's syndrome, osteomalaci _Non-compliance with diet and supplementation _changes in physical activity

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done by the use of computer-generated random table.

Blinding (investigator's opinion)

Double blinded

Blinding description

Prescribing supplement and placebo by a researcher without knowledge of its type, as well as taking it by the participants in the study without their knowledge. In order to minimize bias in the intervention, vitamin D and placebo pearls were named as A or B by factory then put in sealed envelope by a third person.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Yazd university of Medical Sciences

Street address

Campus of Sadoughi University of Medical Sciences, Shohadaye Gomnam Blv, Yazd

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2016-11-26, 1395/09/06

Ethics committee reference number

IR.SSU.SPH.REC.1395.96

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

polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

2**Description of health condition studied****ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

25OHD (25-hydroxy vitamin D)

Timepoint

Before and after 12 weeks treatment

Method of measurement

Using ELISA

Secondary outcomes

1

Description

Leptin serum level

Timepoint

Before and after 12 weeks treatment

Method of measurement

Using ELISA

2

Description

Weight

Timepoint

Before and after 12 weeks treatment

Method of measurement

OMRON scale with an accuracy of 0.1kg

3

Description

Body mass index

Timepoint

Before and after 12 weeks treatment

Method of measurement

weight/ height*height

4

Description

Weist circumference

Timepoint

Before and after 12 weeks treatment

Method of measurement

By meter in cm

5

Description

hip circumference

Timepoint

Before and after 12 weeks treatment

Method of measurement

By meter in cm

6

Description

percent of body fat, percent of free fat mass

Timepoint

Before and after 12 weeks treatment

Method of measurement

Body composition device

Intervention groups

1

Description

Intervention group: participants in this group received weight loss diet plus 50000 IU/week vitamin D3 supplementation for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: participants in this group received weight loss diet plus placebo (including paraffin) /week for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Izadi hospital

Full name of responsible person

Samira Jafari Sfidvajani

Street address

alley 12, Golestan avenue, Amin boulevard

City

Qom

Province

Ghous

Postal code

3716698956

Phone

+98 25 3294 2208

Email

samira.jafari67@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr Azadeh Najarzadeh

Street address

Shahid Sadoughi University of Medical Sciences, Alem square

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3820 9104

Email

azadehnajarzadeh@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Samira Jafari-Sfidvajani

Position

MSc of Nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Alley 12, Golestan avenue, Amin boulevard

City

Qom

Province

Ghoum

Postal code

3716698956

Phone

+98 25 3294 2208

Email

samira.jafari67@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Azadeh Najarzadeh

Position

PhD in Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Shahid Sadoughi University of Medical Sciences, Alem square

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3820 9104

Email

azadehnajarzadeh@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Samira Jafari-Sfidvajani

Position

MSc of nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Alley 12, Golestan avenue, Amin boulevard

City

Qom

Province

Ghoum

Postal code

3716698956

Phone

+98 25 3294 2208

Email

samira.jafari67@gmail.com

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

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Not applicable

Title and more details about the data/document

Data report will be shared after publishing the paper.

When the data will become available and for how long

Six months after publish

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Using for Meta-analysis

From where data/document is obtainable

Center nutrition, public health, univercity of medical scienccies yazd Tel: 009835 31492239 Email: azadehnajarzadeh@gmail.com Azadenadjarzadeh

What processes are involved for a request to access data/document

It will be sent two weeks after the receipt of the email

with the consent of the co-workers
Comments