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 para-thyroid, 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
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Iran (Islamic Republic of)
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+98 912 202 2817
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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
Befor and after 12 weeks treatment
Method of measurement
Using ELISA

Secondary outcomes

1

Description
Leptin serum level
Timepoint
Befor and after 12 weeks treatment
Method of measurement
Using ELISA

2

Description
Weight
Timepoint
Befor and after 12 weeks treatment
Method of measurement
OMRON scale with an accuracy of 0.1kg

3

Description
Body mass index
Timepoint
Befor and after 12 weeks treatment
Method of measurement
weight/ height*height

4

Description
Weist circumference
Timepoint
Befor and after 12 weeks treatment
Method of measurement
By meter in cm

5

Description
hip circumference
Timepoint
Befor and after 12 weeks treatment
Method of measurement
By meter in cm

6

Description
percent of body fat, percent of free fat mass
Timepoint
Befor 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
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3716698956
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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
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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
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Person responsible for updating data

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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 sciencies 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