Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Compare The Effect of Vitamin D3 With 2 Different Doses on Metabolic Disorders in Women With Poly-cystic Ovary Syndrome and Vitamin D Deficiency.

Protocol summary

Summary

This study is a prospective and randomized single-blind clinical trial. The aim of this study is to compare the effect of vitamin D3 with 2 different doses on metabolic disorders in women with polycystic ovary syndrome and vitamin D deficiency. Total of sample size is 124 woman with ages: 18-45 years old. The patients with malabsorption, chronic renal failure, cirrhosis, pancreatitis, nephrotic syndrome, cancer, hyperprolactinemia, cushing's syndrome, congenital adrenal hyperplasia, androgen secreting tumors and pregnant and lactating patients will be excluded. The patients are randomly divided into two groups. Patients do not know about the protocol of the study and type of drug. First group receives oral dose of 50,000 IU of vitamin D once per week for 8 weeks. Second group receives oral dose of 50,000 IU of vitamin D once per month for 2 months. In both methods, 1000 mg of calcium carbonate are given twice daily throughout the treatment period. Patients basic information such as age and BMI, serum triglyceride, LDL, HDL, total cholesterol, fasting blood sugar, fasting insulin levels, vitamin D will be recorded in both groups before treatment and after the treatment period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100824426N1**
Registration date: **2015-10-22, 1394/07/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-10-22, 1394/07/30

Registrant information

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Ahvaz Jundishapur University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-05-31, 1394/03/10

Expected recruitment end date

2015-10-02, 1394/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare The Effect of Vitamin D3 With 2 Different Doses on Metabolic Disorders in Women With Poly-cystic Ovary Syndrome and Vitamin D Deficiency.

Public title

The Effect of Vitamin D3 on Metabolic Disorders in Women With Ovarian Cysts and Vitamin D Deficiency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Women with poly-cystic ovary

syndrome; vitamin D less than 30 ng/ml . Exclusion Criteria: Chronic diseases such as malabsorption, chronic renal failure, cirrhosis, pancreatitis, nephrotic syndrome; malignancies; hyperprolactimenia; cushing's syndrome; congenital adrenal hyperplasia; androgen secreting tumors; using Drugs that affect metabolic parameters such as metformin, corticosteroids in the previous three months; using vitamin D and calcium and multivitamins in the last six months.

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **124**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
To randomization: Consecutive odd and even numbers are assigned to patients. oral dose of 50,000 IU of vitamin D once per week for 8 weeks and oral dose of 50,000 IU of vitamin D once per month for 2 months are administered to odd and even numbered, respectively.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences

Street address
Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City
Ahvaz

Postal code

Approval date
2015-05-30, 1394/03/09

Ethics committee reference number
ir.ajums.REC.1394.16

Health conditions studied

1

Description of health condition studied
Vitamin D

ICD-10 code
E55.9

ICD-10 code description
Avitaminosis D

Primary outcomes

1

Description
Body mass index (BMI)

Timepoint
Before treatment and after completion of treatment in the eighth week

Method of measurement
By Using the formula: weight (kg) / the square of the height (m)

2

Description
The level of vitamin D

Timepoint
Before treatment and after completion of treatment in the eighth week

Method of measurement
Venous sampling and sent to the laboratory

3

Description
The serum levels of triglycerides, LDL, HDL, Total cholesterol

Timepoint
Before treatment and after completion of treatment in the eighth week

Method of measurement
Venous sampling and sent to the laboratory

4

Description
Fasting blood glucose levels

Timepoint
Before treatment and after completion of treatment in the eighth week

Method of measurement
Venous sampling and sent to the laboratory

5

Description
Fasting insulin levels

Timepoint
Before treatment and after completion of treatment in the eighth week

Method of measurement
Venous sampling and sent to the laboratory

Secondary outcomes

empty

Intervention groups

1

Description
Group I: Prescription oral dose of 50,000 IU of vitamin D once per week for 8 weeks.
Category
Treatment - Drugs

2

Description
Group II: Prescription oral dose of 50,000 IU of vitamin D once per month for 2 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khomeini Hospital
Full name of responsible person
Bahman Ghaderian
Street address
Khomeini Hospital, Shahid Ahvazian St., Ahvaz
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2

Recruitment center
Name of recruitment center
Golestan Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Nader Saki
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Vice chancellor For Research Of Ahvaz Jondishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz
City
Ahvaz
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 Of Ahvaz Jundishapur University of Medical Sciences
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

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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