

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Name

Leila Moradi

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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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; hyperprolactinemia; 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

City

Ahvaz

2

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Mahmod Latifi

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Golestan Hospital, Farvardin st., Golestan, Ahvaz

City

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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

Street address

Vice chancellor For Research Of Ahvaz Jundishapur 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

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Leila Moradi

Position

fellowship in endocrinology and metabolic diseases

Other areas of specialty/work

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Subspecialty Endocrinology and Metabolism

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Sharing plan

Person responsible for updating data

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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