

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Assessment of vitamin D oral supplementation on insulin resistance, visceral fat and adiponectin in women with polycystic ovary syndrome and hypovitaminosis D

Protocol summary

Summary

Object: Assessment of vitamin D oral supplementation on insulin resistance, visceral fat and Adiponectin in women with polycystic ovary syndrome and hypovitaminosis D
Design: Single-blind randomized clinical trial (in patient).
Methods: We conducted a single-blind (in patients), randomized clinical trial. Forty-four women are selected with baseline polycystic ovary syndrome. Participants were randomly assigned to two groups: The intervention group (8 vitamin D3 capsule 50000 IU during 2 month (1 capsule in the week after lunch) and the Control group: 8 placebo capsule (Paraffinedible) during 2 month (1 capsule in the week after lunch). ELISA, HOMA-IR, HOMA-B, ECL, QUICKI methods was used for data analysis.
Inclusion criteria: Women with pcos according rotterdam criteria; Vitamin D deficiency ($x \leq 20$ ng); OCPs consumer; Age between 20 to 38. **Exclude criteria:** Under 20 and over 38 years old; Neoplastic disorders; hepatic, renal; cardiovascular; malabsorptive and pregnancy; Those who consume vitamin D and taking antidiabetic drugs; People who follow a special diet pattern had specific physical activity
Variables: Insulin resistant; visceral fat; adiponectin were measured and compared between two groups before and the end of intervention period. Also 24 recall and exposure to sunlight questioner during the intervention were completed.
Intervention/Control: Intervention: 8 vitamin D3 capsule 50000 IU during 2 month (1 capsule in the week after lunch). Control: 8 placebo capsule (Paraffinedible) during 2 month (1 capsule in the week after lunch)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101030248N1**
Registration date: **2016-11-17, 1395/08/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-17, 1395/08/27

Registrant information

Name

Sakineh Nouri saeidlou

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 44 3276 6825

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Recruitment status

Recruitment complete

Funding source

government

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-08-20, 1395/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of vitamin D oral supplementation on insulin resistance, visceral fat and adiponectin in women with polycystic ovary syndrome and hypovitaminosis D

Public title

Assessment of vitamin D oral supplementation on insulin resistance, visceral fat and adiponectin in women with polycystic ovary syndrome and hypovitaminosis D

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Women with pcos according rotterdam criteria; Vitamin D deficiency ($x < 20$ ng); OCPs consumer; Age between 20 to 38 Exclude criteria: Under 20 and over 38 years old; Neoplastic disorders; hepatic; renal; cardiovascular; malabsorptive and pregnancy; Those who consume vitamin D and taking antidiabetic drugs; People who follow a special diet pattern had specific physical activity

Age

From **20 years** old to **38 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

In order to avoid the possible effect of awareness of allocation to treatment or placebo groups a single blind design was used which only researcher was aware of randomizing into two groups. According to the number of randomized table, we put patient into two groups and they did not know any things about this.

Secondary Ids

empty

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

Ethics committee of Urmia University of Medical Sciences

Street address

University Campus: Pardis Nazlou, 11 km of Nazlou Road, Urmia, Iran Phone: +98 44 3223 4897 Fax: +98 44 322 290 59

City

Urmia

Postal code**Approval date**

2016-05-18, 1395/02/29

Ethics committee reference number

ir.umsu.rec.1395.100

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**

insulin resistance

Timepoint

before intervention-after intervention (2 month later)

Method of measurement

insulin resistance: HOMA-IR, HOMA-B ,QUICKI

2**Description**

visceral fat

Timepoint

before intervention-after intervention(2 month later)

Method of measurement

visceral fat :BIA(Inbody 770)

3**Description**

Adiponectin

Timepoint

before intervention-after intervention(2 month later)

Method of measurement

Adiponectin.: serum adiponectin.

Secondary outcomes**1****Description**

Sun exposure and physical activity

Timepoint

during intervention

Method of measurement

The questionnaire sunlight

2**Description**

Diet

Timepoint

week 4-6-8

Method of measurement

24-hour recalls

Intervention groups**1****Description**

Intervention: 8 vitamin D3 capsule 50000 IU during 2 month (1 capsule in the week after lunch)

Category

Treatment - Drugs

2**Description**

Control: 8 placebo capsule(Paraffinedible) during 2 month (1 capsule in the week after lunch)

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Motaharey Hospital

Full name of responsible person

Dr. Taherh Behrozey Lak

Street address**City**

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Urmia University of Medical Sciences

Full name of responsible person

Dr Iraj Mohebi

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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

Vice chancellor for research, Urmia 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**

Urmia University of Medical Sciences

Full name of responsible person

Dr.Sakineh Nouri Saeidlou

Position

PhD.Nutrition

Other areas of specialty/work**Street address**

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Full name of responsible person

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empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty