Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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. Fouty_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 rotterdom 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 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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Recruitment status

Recruitment complete

Funding source

goverment

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 supplementationon 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 rotterdom 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 awareness of randomizing into two groups. According to the number's 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
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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
Urmia

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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City
Urmia
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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