Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Clinical and laboratory Efects of vitamin D supplementation in adolescent with polycystic ovarian syndrome and vitamin D deficiency

Protocol summary

Summary

Objective: To determine the effect of vitamin D in adolescents with polycystic ovary syndrome have vitamin D deficiency. Design, Setting and conduct: Random; alternating block method; single-blind; two intervention and control groups. Inclusion criteria: age 14 to 18 years old; people with impaired ovulation or anovulation for oligoovulation (oligo- and / or anovulation); 2 and 3 Hyperandrogenemia clinical hyperandrogenism or There polycystic ovarian morphology on ultrasound and they are deficient in vitamin D, and the study Azargoon et al(1) known as polycystic ovarian syndrome. Exclusion criteria: people who do not have full consent to participate in this study; Those who did not use vitamin D to regular weekly; Those in the intervention of the symptoms of polycystic ovary syndrome drugs such as birth control pills, metformin, medroxyprogesterone and progesterone intramuscular injection except in the event of amenorrhea has 45 days from the previous cycle dose of 200 mg for the induction periods are used. Intervention and main outcome measures: In the intervention group, weekly 50000 units of vitamin D and the control group, the placebo treatment in both groups 8 weeks will be (based on studies of Thomson et al. 2012); intervention, in the first day of bleeding, weekly and then monthly up to 8 weeks to two months continues. Methods of collecting data with demographic questions, blood pressure and check list data obtained from in vitro assays (FBS and fasting insulin, TG, HDL and LH, FSH, testosterone and 25 hydroxyvitamin D3) and clinical (hirsutism, acne, menstrual pattern) and ultrasound done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016021125732N2**

Registration date: **2016-05-01, 1395/02/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-01, 1395/02/12

Registrant information

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Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

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Recruitment status

Recruitment complete

Funding source

Deputy of research and technology Semnan University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

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

Clinical and laboratory Efects of vitamin D supplementation in adolescent with polycystic ovarian syndrome and vitamin D deficiency

Public title
Clinical and laboratory Efects of vitamin D supplementation in adolescent with polycystic ovarian syndrome and vitamin D deficiency
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age 14 to 18 years old; people with impaired ovulation or anovulation for oligoovulation (oligo- and / or anovulation); 2 and 3 Hyperandrogenemia clinical hyperandrogenism or There polycystic ovarian morphology on ultrasound and they are deficient in vitamin D, and the study Azargoon et al(1) known as polycystic ovarian syndrome. Exclusion criteria: people who do not have full consent to participate in this study; Those who did not use vitamin D to regular weekly; Those in the intervention of the symptoms of polycystic ovary syndrome drugs such as birth control pills, metformin, medroxyprogesterone and progesterone intramuscular injection except in the event of amenorrhea has 45 days from the previous cycle dose of 200 mg for the induction periods are used.
Age
From **80 years** old to **76 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Semnan University of Medical sciences
Street address
Semnan University of Medical Sciences
City
Semnan
Postal code
Approval date
2015-08-25, 1394/06/03
Ethics committee reference number
IR.SEMUMS.REC.1394.76

Health conditions studied

1

Description of health condition studied
Adolescent with polycystic ovarian syndrome and vitamin D deficiency
ICD-10 code
E28.2 ; E2
ICD-10 code description
Polycystic ovarian syndrome; Ovarian dysfunction, unspecified

Primary outcomes

1

Description
Measuring vitamin D
Timepoint
Started
Method of measurement
Laboratory - using the kit for measuring vitamin D, with EUROIMMUN, the UK

Secondary outcomes

1

Description
Ultrasonography
Timepoint
In 3 to 5 days of menstrual bleeding
Method of measurement
Abdominal Ultrasonography, by one sonographer

2

Description
Measuring vitamin D
Timepoint
After the intervention
Method of measurement
Laboratory - using the kit for measuring vitamin D, with EUROIMMUN, the UK

3

Description
Blood pressure measurement
Timepoint
After the intervention
Method of measurement
Manometer using a pan with 710 made in Taiwan, the left arm in a sitting position

4

Description
Measure weight
Timepoint
After the intervention
Method of measurement
Scales with 100 g

5

Description
Measuring stature
Timepoint
After the intervention
Method of measurement
Using tape measure with an accuracy of one centimeter

Intervention groups

1

Description
In the intervention group, 50 000 IU of vitamin D weekly for 8 weeks will be given. PCOS symptoms, patients should not interfere with effective drugs such as oral contraceptives COCS, metformin, medroxyprogesterone and so on. The only injectable progesterone injections in case of amenorrhea has 45 days from the previous cycle dose of 200 mg intramuscularly for induction menstruation is used.
Category
Prevention

2

Description
The control group, placebo will be given for 8 weeks. PCOS symptoms, patients should not interfere with effective drugs such as oral contraceptives COCS, metformin, medroxyprogesterone and so on. The only injectable progesterone injections in case of amenorrhea has 45 days from the previous cycle dose of 200 mg intramuscularly for induction menstruation is used.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospital AmirAlMomenin Semnan
Full name of responsible person
Dr Mojgan Rahmanian
Street address
Hospital AmirAlMomenin, Mostafa Khomeini Blvd, Semnan
City
Semnan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Semnan University of Medical sciences
Full name of responsible person
Dr Mojgan Rahmanian
Street address
Hospital AmirAlMomenin, Mostafa Khomeini Blvd, Semnan
City
Semnan
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, Semnan 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
Semnan University of Medical Sciences, Vice Chancellor for Research, Semnan
Full name of responsible person
Dr Mojgan Rahmanian
Position
Obstetrics and Gynecology
Other areas of specialty/work
Street address
Hospital AmirAlMomenin, Mostafa Khomeini Blvd, Semnan
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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