

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Assessment effect of vitamin D supplementation on insulin resistance in women with poly cystic ovarian syndrome

Protocol summary

Registration timing: **registered_while_recruiting**

Summary

Goal: Assessment effect of vitamin D supplementation on insulin resistance in women with poly cystic ovarian syndrome Drawings: The diagnosis of PCOS was based on the Rotterdam criteria, which necessitated 2 of the following 3 features:1. oligoovulation and anovulation (less than 6 times in 12 months) 2. clinical or biochemical signs of hyperandrogenism such as acne, alopecia or high androgen level 3. polycystic ovaries on ultrasound examination and the patients have vitamin D deficiency were included. Design: The questionnaires were included height, weight, body mass index, waist, menstruation pattern, infertility.Tests, fasting glucose, fasting insulin, insulin resistance index were measured in these patients.Inclusion criteria: Women who were between 20 and 40 years old, were vitamin D deficient, and had PCOS diagnosed by a gynecologist Exclusion criteria: Patients who were diagnosed with Cushing syndrome, congenital adrenal hyperplasia, hyperprolactinemia, hypothyroidism, hyperthyroidism, androgen secreting tumor, all systemic disease affect vitamin D level such as liver disease, renal dysfunction, malabsorption syndrome, alcoholism, lactation, pregnancy, medications known to affect metabolic parameters, such as metformin and corticosteroid drugs,vitamin D, and serum calcium Intervention: The patients received a single dose of vitamin D and the piolt checked again two months after treatment.Written consent form was obtained from all patients. Primary outcome measure: Fasting glucose Fasting insulin HOMA IR Secondary outcome measure: Height, Weight, 25 hydroxy vitamin D, Body Mass Index

Last update:

Update count: **0**

Registration date

2014-12-12, 1393/09/21

Registrant information

Name

Saghar Salehpour

Name of organization / entity

Shahid Behshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2558

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Science

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment effect of vitamin D supplementation on insulin resistance in women with poly cystic ovarian syndrome

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100619426N1**

Registration date: **2014-12-12, 1393/09/21**

Public title

Assessment effect of vitamin D supplementation on insulin resistance in women with poly cystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Women who were between 20 and 40 years old, were vitamin D deficient, and had PCOS diagnosed by a gynecologist Exclusion criteria: Patients who were diagnosed with Cushing syndrome, congenital adrenal hyperplasia, hyperprolactinemia, hypothyroidism, hyperthyroidism, androgen secreting tumor, all systemic disease affect vitamin D level such as liver disease, renal dysfunction, malabsorption syndrome, alcoholism, lactation, pregnancy, medications known to affect metabolic parameters, such as metformin and corticosteroid drugs, vitamin D, and serum calcium

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Vice chancellor for research, Shahid Beheshti University of Medical Science

Street address

SBMU_ School of medicine, 3rd floor, Velenjak , Shahid Chamran highway, Tehran

City

Tehran

Postal code

193954719

Approval date

2014-05-18, 1393/02/28

Ethics committee reference number

SBMU.REC.1393.40

Health conditions studied**1****Description of health condition studied**

Polycystic Ovarian Syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Fasting glucose

Timepoint

Before intervention and two months after vitamin D injection

Method of measurement

Blood serum

2**Description**

Fasting insulin

Timepoint

Before intervention and two months after vitamin D injection

Method of measurement

Blood serum

3**Description**

HOMA IR

Timepoint

Before intervention and two months after vitamin D injection

Method of measurement

Calculation by formula

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

Height

Timepoint

Before intervention and two months after vitamin D injection

Method of measurement

Meter

2**Description**

Weight

Timepoint

Before intervention and two months after vitamin D injection

Method of measurement

Balance

3

Description

25 hydroxy vitamin D

Timepoint

Before intervention and two months after vitamin D injection

Method of measurement

Blood serum

4

Description

Body Mass Index

Timepoint

Before intervention and two months after vitamin D injection

Method of measurement

Formola

Intervention groups

1

Description

Intervention: The questionnaires were included height, weight, body mass index, waist, menstruation pattern, infertility. Tests, fasting glucose, fasting insulin, insulin resistance index were measured in these patients. The patients received a single dose of vitamin D(300000 IU) and the piolt checked again two months after treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility & Reproductive Health Research Center
Shahid Beheshti University of Medical Science

Full name of responsible person

Zahra Sadeghzadeh

Street address

Taleghani hospital , Velenjak, Shahid Chamran highway, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti
University of Medical Science

Full name of responsible person

Mrs Zahra Khateri

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SBMU, School of Medicine, 3td floor, Velenjak , Shahid Chamran highway, Tehran

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Tehran

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, Shahid Beheshti University of Medical Science

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

Infertility & Reproductive Health Research Centre -
Shahid Beheshti of Medical Science

Full name of responsible person

Dr Saghar salehpour

Position

Associate professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Infertility & Reproductive Health Research Centre -
Shahid Beheshti of Medical Science

Full name of responsible person

Dr Sedighe Hosseini

Position

Gynecologist

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

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Infertility & Reproductive Health Research Centre - Shahid Beheshti of Medical Science

Full name of responsible person

Dr Saghar Salehpour

Position

Associate professor

Other areas of specialty/work**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