Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of administration Calcium-Vitamin D and Metformin in Regulating Menstrual Cycle in Polycystic Ovarian Syndrome

Protocol summary

Summary

Objectives: this article is aimed to study the effects of two different drugs in menstrual cycle. The research was done with a focus to 20 to 40 years old patients who had referred to Kosar hospital and were diagnosed PCO by criteria Rotherdam 2003 with symptoms such as anovulation or chronic oligomenorrhea. Design: randomized, single-blind, single-center. Setting and conduct: group A, calcium D pills and group B, metformin tablets is administered. Participants including major eligibility criteria: Inclusion criteria include presence of polycystic ovary and anovulation or choronic oligomenorrhea; exclusion criteria include thyroid disorders and hyperprolactinemia. Intervention: calcium D group (A), 1000mg calcium, vitamin D 400 IU and metformin group (B), 500mg metformin 3 times per day for a six months period is administered. Main outcome measures variable: menstrual cycle is evaluated after consumption of drug.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705084850N4**
Registration date: **2017-06-25, 1396/04/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-25, 1396/04/04

Registrant information

Name

Shokoh Alsadat Haji Seyed Abotorabi

Name of organization / entity

Qazvin,University of Medical Sciences & Health Services

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and technology, Qazvin University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of administration Calcium-Vitamin D and Metformin in Regulating Menstrual Cycle in Polycystic Ovarian Syndrome

Public title

Comparison of the effect of administration Calcium-Vitamin D and Metformin in Regulating Menstrual Cycle in person with an ovulation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the patient with pcos according to roterdam 2003 criteria with anovulation and chronic oligo ovulation and Exclusion criteria: are hyperparathyroidism; hyperprolactinemia.

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: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Bahonar Blvd, Qazvin, Iran

City

Qazvin

Postal code

Approval date

2011-08-17, 1390/05/26

Ethics committee reference number

20/3271/د

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

Mean of interval menstrual cycles

Timepoint

Interval menstrual cycles

Method of measurement

Questionnaire

Secondary outcomes

1

Description

menstrual cycles interval

Timepoint

In six menstrual cycles

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention/Control 1: Calcium-D tablet (1000mg Calcium, Vitamin D 400 IU)

Category

Treatment - Drugs

2

Description

Intervention/Control 2: Metformin tablet 500 mg 3 times a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Dr Shokohossadat Abotorabi

Street address

Kowsar Hospital, Taleghani St, Qazvin, Iran

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research of Qazvin University of Medical Sciences

Full name of responsible person

Dr Amir Peymani

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City

Qazvin

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 Qazvin 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
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shabotorabi@qums.ac.ir abotorabi4242@yahoo.com
Web page address

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