

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Calcium and Vit D supplementation effects on menstrual cycle in Poly Cystic Ovary Syndrome women with National Institute Of Health criteria

Protocol summary

Registration timing: **registered_while_recruiting**

Summary

this study is a double-blind, clinical trial prospective study, based on National Institute Of Health (1990) criteria that involve: 1-Chronic Anovulation 2-clinical or biochemical evidence of hyper Androgenism and 3-role out of other causes women with Poly Cystic Ovary Syndrome in range of 15-40 years of age determine that their Calcium (8.7-10.2mg/dl) and Creatinine (0.5-0.9mg/dl) serum are normal and Vitamin D3 serum is lower than normal {30ng/ml} (is determine with check of blood sampling) they enroll in study and divide in 4 groups of 20 patients base on a random number table, and for 4 months treat and follow up the following: 1-group 1 :treat with Metformin {1500mg/day}. 2-group 2 treat with Metformin {with dose above} plus Calcium {1000mg/day} and Pearl vitamin D3 { 50000IU/ every two weeks}. 3-group 3 treat with Calcium and pearl vitamin D3 {with doses above} and 4-group 4: receive Placebo {low calory sweetener tablets} with writing of menstrual days by patients (interval between regular menses is 24-35 days) and forasmuch ovulation is criteria for regular mense and ovulation is determine with dominant follicle {equal or upper than 14mm}; so in these patients do sonography of uterus and adenex in first and the end of period to evaluate dominant follicle. exclude criteria are: 1-Cushing syndrome 2-Renal Failure (Creatinine equal or upper than 1.5mg/dl) 3-Ovary and Adrenal Tumor that secreted Androgen 4-primary and secondary hyper Parathyroidism 5-Osteomalasia 6-Cancers 7-Gastrectomy 8-Mental Retardation 9-Anti Convulsive Drugs 10-Congenital Adrenal Hyperplasia and secondary exclude criteria are Diarrhea, Vomiting and severe abdominal Distention.

Last update:

Update count: **0**

Registration date

2013-10-03, 1392/07/11

Registrant information

Name

Hatav Ghasemi Tehrani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 913 113 4081

Email address

tehrani@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University Of Medical Science

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308037513N3**

Registration date: **2013-10-03, 1392/07/11**

Scientific title

Calcium and Vit D supplementation effects on menstrual cycle in Poly Cystic Ovary Syndrome women with National Institute Of Health criteria

Public title

Calcium and Vitamin D supplementation effects on menstrual cycle in Poly Cystic Ovary Syndrome women

Purpose

Treatment

Inclusion/Exclusion criteria

include criteria:women in the range of 15-40 years of the age with Poly Cystic Ovary Syndrome that their Calcium(8.7-10.2mg/dl) and Creatinin(0.5-0.9mg/dl) serum are in normal range and they have vitamin D3 serum lower than normal{30ng/ml}. exclude criteria: Cushing Syndrome:Renal Failur(Creatinin equal or upper than 1.5mg/dl) Ovary and Adrenal Tumor that secreted Androgen:Primary and Secondary hyper Parathyroidism:Osteomalasia:Cancers:Gastrectomy:Men tal Retardation:Anti Convulsive Drugs:Congenital Adrenal Hyperplasia and secondary exclude criteria are Diarrhea:Vomiting:severe abdominal Distention.

Age

From **15 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)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University Of Medical Sciences

Street address

Hezar Jarib Street

City

Isfahan

Postal code

8174673461

Approval date

2013-06-22, 1392/04/01

Ethics committee reference number

392196

Health conditions studied

1

Description of health condition studied

Poly Cystic Ovary Syndrome

ICD-10 code

e28.2

ICD-10 code description

sclerocystic ovary syndrome-stein leventhal syndrome

Primary outcomes

1

Description

regularity of menstrual cycle

Timepoint

monthly

Method of measurement

with write of menstrual days by patient{interval of regular menses is 24-35days}

2

Description

regularity of menstrual cycle

Timepoint

in first and the end of period of treatment

Method of measurement

do sonography for determine of dominant follicle that it is criteria for ovulation and regularity of mense

Secondary outcomes

1

Description

weight changes

Timepoint

before start of study and the end of study

Method of measurement

do with determinant of body mass index{BMI}

Intervention groups

1

Description

first group{control group}:treat with Metformin{1500mg/day} orally for 4 months

Category

Treatment - Drugs

2

Description

group 2{control group}: treat with Metformin{1500mg/day}plus Calcium{1000mg/day} and Pearl vitamin D3{ 50000IU/ every two weeks} orally for 4 months.

Category

Treatment - Drugs

3

Description

group 3{case group}: treat with Calcium{1000mg/day}and Pearl vitamin D3 {50000IU/every two weeks} orally for 4 months.

Category

Treatment - Drugs

4

Description

group 4{control group}: recieve placebo{low calory sweetener tablets} 2 times a day orally for 4 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic Of Obstetrics & Gynecology Of Beheshti Hospital

Full name of responsible person

Dr Somayeh SHahsavary-Obstetrics & Gynecology Resident

Street address

Felezi bridge-SHahid Motahary Street

City

Isfahan

2

Recruitment center

Name of recruitment center

Clinic Of Obstetrics & Gynecology Of Alzahra Hospital

Full name of responsible person

Dr Somayeh SHahsavary-Obstetrics& Gynecology Resident

Street address

Hakim Nezami 3way-Sofeh Boulevard

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University Of Medical Sciences

Full name of responsible person

taleb azarm MD-research assistant in school of medicine of isfahan university of medical sciences

Street address

Hezar Jarib Street

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Isfahan

Grant name

12/4/1321پ

Grant code / Reference number

392196

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan 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

Isfahan University Of Medical Sciences

Full name of responsible person

Somayeh SHahsavary Alavijeh

Position

Obstetrics & Gynecology Resident

Other areas of specialty/work

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Full name of responsible person

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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