Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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 Calcum(8.7-10.2mg/dl) and Creatinin(0.5-0.9mg/dl) serum are normal and Viamin D3 serum is lower than normal{30ngr/ml}(is determine with check of blood sampling) they enroll in study and devide 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: recieve Placebo{low calory sweetener tablets} with writing of menstural 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 folicle{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 folicle. exclude criteria are: 1-Cushing syndrome 2-Renal Failure(Creatinin 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-Gasterectomy 8-Mental Retardation 9-Anti Convuisive Drugs 10-Congenital Adrenal Hyperplasia and secondary exclude criteria are Diarrhea.Vomiting and severe abdominal Distention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308037513N3**

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

Registration timing: **registered_while_recruiting**

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

Scientific title

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

Public title

Calcium and Vitamin D supplemention effects on menstrual cycle in Poly Systic 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 Calcum(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{30ngr/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؛Gasterectomy؛Mental Retardation؛Anti Convuisive 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 Universuty 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 menstural cycle

Timepoint

monthly

Method of measurement

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

2

Description

regularity of menstural cycle

Timepoint

in first and the end of period of treatment

Method of measurement

do sonography for determine of dominant folicle 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
City
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
Street address
Unit7, Gol Mohammadi building, Golriz Street, Gol Afshan street, Sepah Avenue, KHaneh Isfahan---
City
Isfahan
Postal code
8194844419
Phone
+98 31 1434 8124
Fax
+98 43 47906
Email
drsomayeh@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan University Of Medical Sciences
Full name of responsible person
Dr Hatav GHasemi Tehrani
Position
Obstetrics & Gynecologist-Assistant Professor Of Obstetrics & Gynecology
Other areas of specialty/work
Street address
Number 54, Yas Impasse, Golestan 2, after GHadir Bridge, Sepahsalar Street
City

Isfahan
Postal code
8166834161
Phone
+98 31 1630 5630
Fax
+98 63 06321
Email
Tehrani@med.mui.ac.ir
Web page address

Person responsible for updating data

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
Street address
Unit7, Gol Mohammadi building, Golriz Street, Gol Afshan street, Sepah Avenue, KHaneh Isfahan
City
Isfahan
Postal code
8194844419
Phone
+98 31 1434 8124
Fax
+98 43 47906
Email
drsomayeh@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