Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of calcitriol and metformin treatment on improvement of clinical and metabolic complications of polycystic ovary syndrome

Protocol summary

Summary

aim: Prevalence of poly cystic ovarian syndrome (PCOs) in reproductive age women is about 10 %. There is a lot of morbidity due to this syndrome. Vitamin D deficiency is a common problem in the world and especially in Iran. Because of probable role of activated vitamin D on induction of insulin secretion and reduction in insulin resistance and the effect of hyperinsulinemia on elevation of free androgens; we designed to evaluate the effect of active form of vitamin D on control of PCOS clinical and metabolic complications. design:in a randomized clinical trial 51 untreated PCOS with Presence of two criteria of these three : 1 – Anovulation or oligoovulation (or menstrual cycle less than 6 cycles in 12 month) 2 – Clinical or biochemical symptoms of hyperandrogenemia include: acne, hirsutism , alopecia or increased serum androgen levels . 3- View of polycystic ovary with 12 follicles or more in each ovary with diameter between 2-9 mm or increased ovarian volume more than 10 cm3 by ultrasound will selected. For other cause of hyperandrogenism including : congenital adrenal hyperplasia , Cushing's syndrome , hyperprolactinemia, hypothyroidism and tumors that secrete androgens will excluded by laboratory markers.With regard to the check of the 25 hydroxy vitamin D level in patients , we exclude all the patients that had systemic factors that interfere on vitamin D level like : history of renal disease , hepatic disease , malabsorption, alcoholism , breastfeeding , pregnancy and all the people who used drugs that effective on vitamin D level like : anti epileptic agents , supplement of calcium and vitamins and glucocorticoids women randomly divide to three groups. Treatment with calcitriol consist of 1, 25 hydroxy vitamin D (zahravy company) 0.25 mcg / bid , metformin(500 mg/ bid) (hexal company), placebo(consist of starch) two tablet in day will started for each one groups for three month. main outcome: After three months, assessment for improvement in clinical (ovulation) and metabolic (fasting blood glucose, glucose tolerance test, insulin resistance and androgen levels) will performed

General information

Acronym

PCOS and vitamin D

IRCT registration information

IRCT registration number: **IRCT201108074167N4**
Registration date: **2012-01-21, 1390/11/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-01-21, 1390/11/01

Registrant information

Name
Shokoufeh Bonakdaran
Name of organization / entity
Endocrine Research Center
Country
Iran (Islamic Republic of)
Phone
+98 51 1801 2976
Email address
bonakdaransh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2011-09-20, 1390/06/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of calcitriol and metformin treatment on improvement of clinical and metabolic complications of polycystic ovary syndrome

Public title
Effect of calcitriol in PCOS
Purpose
Treatment
Inclusion/Exclusion criteria
Presence of two criteria of these three was necessary: 1 – Anovulation or oligoovulation (or menstrual cycle less than 6 cycles in 12 month) 2 – Clinical or biochemical symptoms of hyperandrogenemia include: acne, hirsutism , alopecia or increased serum androgen levels . 3- View of polycystic ovary with 12 follicles or more in each ovary with diameter between 2-9 mm or increased ovarian volume more than 10 cm3 by ultrasound. For other cause of hyperandrogenism including : congenital adrenal hyperplasia , Cushing's syndrome , hyperprolactinemia, hypothyroidism and tumors that secrete androgens were excluded by laboratory markers.With regard to the check of the 25 hydroxy vitamin D level in patients , we excluded all the patients that had systemic factors that interfere on vitamin D level like : history of renal disease , hepatic disease , malabsorption, alcoholism , breastfeeding , pregnancy and all the people who used drugs that effective on vitamin D level like : anti epileptic agents , supplement of calcium and vitamins and glucocorticoids
Age
To **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **51**
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
Vice chancelor for research, Mashhad University of Medical Sciences
Street address
daneshgah street- ghoreshi buliding
City
Mashhad
Postal code
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
89154

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
Insulin resistance
Timepoint
3 months
Method of measurement
Lab data , FBS and insulin level

Secondary outcomes

1

Description
Ovulation
Timepoint
3 months
Method of measurement
Sonography

Intervention groups

1

Description
Metformin, 500 mg/ bid for three months
Category
Treatment - Drugs

2

Description
Calcitriol, 0.25 microgram bid for three months
Category
Treatment - Drugs

3

Description
Placebo, two tablet in day for three months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancelor for research, Mashhad University of Medical Sciences
Full name of responsible person
Dr. Tavakol Afshar
Street address
Ghoreshi buliding, Daneshgah street
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancelor for research, Mashhad 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
Fellowship of endocrinology
Full name of responsible person
Shokoufeh Bonakdaran
Position
Endocrinologist
Other areas of specialty/work
Street address
Ghaem hospital, Endocrine research center
City
Mashhad
Postal code
Phone
+98 51 1801 2976
Fax
Email
bonakdaransh@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Fellowship of endocrinology
Full name of responsible person
Shokoufeh Bonakdaran
Position
Endocrinologist
Other areas of specialty/work
Street address
Ghaem hospital, Endocrine research center
City
Mashhad
Postal code
Phone
+98 51 1801 2976
Fax
Email
bonakdaransh@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Zahra Mazloom Khorasani
Position
Fellowship of endocrinology
Other areas of specialty/work
Street address
Ghaem hospital
City
Mashhad
Postal code
Phone
Fax

Email

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