

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

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

#### Protocol summary

(fasting blood glucose, glucose tolerance test, insulin resistance and androgen levels) will performed

#### 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 cm<sup>3</sup> 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

#### 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 cm<sup>3</sup> 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 chancellor 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 chancellor 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 chancellor 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

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#### 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*