

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effects of Calcium- Vitamine D supplementary on ovulation and fertility outcomes of patients with poly cystic ovary syndrome referring to Infertility Clinic of Imam Khomeini Hospital in 2011 and 2012 for in vitro fertilization

#### Protocol summary

##### Summary

Through a randomized clinical trial, therapeutic impacts of calcium - vit D supplements are to be assessed on infertile women at pregnancy age (according to the Rotterdam Criteria) attending infertility clinic of Vali e Asr of Imam Khomeini Hospital. Inclusion Criteria are as abnormal menstrual cycles (oligomenorrhea or amenorrhea); Sonographically confirmed poly cystic ovary; Hyperandrogenism while the followings were considered as exclusion Criteria: Other medical conditions; Abdominal or pelvic surgeries; abnormal serum levels of Prolactin; Application of Induction-Ovulation methods within the past three months. One hundred consecutive patients will be randomly assigned to either group of receiving Calcium - D supplement (for three month) plus standard treatment or placebo group just receiving standard treatment. At the end of the treatment intervention, growing follicles, fetal grades, and pregnancy will be evaluated for each case and the results then compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112148408N1**  
Registration date: **2012-08-17, 1391/05/27**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-08-17, 1391/05/27

##### Registrant information

##### Name

batool hossein rashidi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6658 1658

##### Email address

mahdian@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Deputy of Research, School of Medicine, Tehran University of Medical Sciences

##### Expected recruitment start date

2012-03-20, 1391/01/01

##### Expected recruitment end date

2013-01-20, 1391/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effects of Calcium- Vitamine D supplementary on ovulation and fertility outcomes of patients with poly cystic ovary syndrome referring to Infertility Clinic of Imam Khomeini Hospital in 2011 and 2012 for in vitro fertilization

##### Public title

Impacts of Calcium- Vitamine D supplementary on Ovulation in poly cystic ovary syndrome

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion Criteria: Abnormal menstrual cycles (oligomenorrhea or amenorrhea); Sonographically confirmed polycystic ovary; Hyperandrogenism  
Exclusion Criteria: Other medical conditions; Abdominal or pelvic surgeries; abnormal serum levels of Prolactin; Application of Induction- Ovulation methods within the past three months

### **Age**

From **18 years** old to **50 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **200**

### **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**

Tehran University of Medical Sciences

##### **Street address**

Research Deputy, Faculty of Medicine, Poursina Street, Keshavarz Blvd

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2013-05-05, 1392/02/15

#### **Ethics committee reference number**

54825/130/90/3

## **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**

Pregnancy

#### **Timepoint**

2 and 12 weeks

#### **Method of measurement**

Sonography and Biochemistry Laboratory

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

in control group they received placebo

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

In intervention group supplementary tablets of 1000 mg Calcium combined with 400 Iu vitamine D is Administered (Orally) twice a day for three months.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Infertility Clinic of Vali Asr Hospital in Imam Khomeini Complex

##### **Full name of responsible person**

Dr batool hossein rashidi

##### **Street address**

Department of Obstetrics and Gynecology, Vali- e - Asr Hospital, Imam Khomeini Hospital Complex, Keshavarz Blv

##### **City**

Tehran

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Dr Shahin Akhondzadeh

**Street address**

Medical School Research Affairs, Poorsina Street,  
Keshavarz Blv

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Azadeh Mahdian

**Position**

Resident of Obstetrics and Gynecology

**Other areas of specialty/work****Street address**

Department of Obstetrics and Gynecology, Vali- e -  
Asr Hospital, Imam Khomeini Hospital Complex,  
Keshavarz Blv

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**Postal code****Phone**

+98 21 6119 2382

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bhrashidi@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Batool Hossein Rashidi

**Position**

professor of Ob& Gyn

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Department of Obstetrics and Gynecology, Vali- e -  
Asr Hospital, Imam Khomeini Hospital Complex,  
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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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Azadeh Mahdian

**Position**

Resident of Obstetrics and Gynecology

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Department of Obstetrics and Gynecology, Vali- e -  
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**City**

Tehran

**Postal code****Phone**

+98 21 6119 2382

**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*