Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Rotterdom 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

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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

Impcats 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 poly cystic 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

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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/د

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr Shahin Akhondzadeh

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Medical School Research Affairs, Poorsina Street, Keshavarz Blv
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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

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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