

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study effect of supplements (magnesium, vitamin D, vitamin C, zinc and calcium) on cardiometabolic factors in infertile women with polycystic ovary syndrome.

Protocol summary

Summary

Objective: To evaluate and compare the efficacy of supplemental magnesium, vitamin D, vitamin C, zinc and calcium on cardiovascular and metabolic factors in infertile women with polycystic ovary syndrome. Design: Randomized, double-blind, without placebo, single center. Sample volume: Five groups of 40-patient-sized. Inclusion criteria: Abnormal menstrual cycles, polycystic ovaries in sonography, chemical or clinical signs of hyper androgenism. Exclusion criteria: History of any underlying and chronic disease, history of pelvic or abdominal surgery, partner's infertility, abnormal level of serum prolactin, smoking, current or previous using of statins in last 2 months, insulin usage, corticosteroid usage, history of neoplastic disease. Systolic and diastolic blood pressure, blood glucose, insulin, total cholesterol, HDL, LDL, testosterone, DHEA sulfate levels sterilized Andrew supplement intake. Interventions: Patients were randomly divided into five groups and thus the treatment is assigned to them: Control group: Will receive only Metformin 100 mg daily Intervention groups: 1- One thousand milligrams of calcium and 400 IU vitamin D twice a day with metformin 100 mg daily 2 - Zinc sulfate capsules daily with metformin 100 mg daily 3 - Tablets of magnesium 250 milligrams daily with metformin 100 mg daily 4 - Vitamin C, two thousand milligrams daily with metformin 100 mg daily Than the patients at baseline and at the end of the treatment, after bearing eight to twelve hours overnight fasting, will be tested for these parameters: Systolic and diastolic blood pressure, blood glucose, insulin, total cholesterol, HDL, LDL, testosterone, DHEA sulfate and serum level of intake supplements. The main outcome of these patients is to improve cardiovascular and metabolic factors.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013110615307N1**

Registration date: **2014-04-05, 1393/01/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-05, 1393/01/16

Registrant information

Name

Roghaieh Anvari Ali Abad

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 7082

Email address

ranvari@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamedan University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study effect of supplements (magnesium, vitamin D, vitamin C, zinc and calcium) on cardiometabolic factors in infertile women with polycystic ovary syndrome.

Public title

Effect of magnesium, vitamin D, vitamin C, zinc and calcium Supplements on cardiometabolic parameters in infertile women with polycystic ovary syndrome.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Abnormal menstrual cycles, polycystic ovaries in sonography, chemical or clinical signs of hyper androgenism. Exclusion criteria: History of any underlying and chronic disease, history of pelvic or abdominal surgery, partner's infertility, abnormal level of serum prolactin, smoking, current or previous using of statins in last 2 months, insuline usage, corticosteroid usage, history of neoplastic disease.

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Hamedan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Fahmide st,
Pajoohesh sq

City

Hamedan

Postal code

3519638686

Approval date

2013-07-04, 1392/04/13

Ethics committee reference number

16/65/9/1049/پ

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**

Heart condition

Timepoint

2 months after intervention

Method of measurement

Echocardiography

Secondary outcomes**1****Description**

Serum lipids level

Timepoint

tow months after intervention

Method of measurement

Patients blood sampel

2**Description**

Serum insullin level

Timepoint

tow months after intervention

Method of measurement

Patients blood samples patients

Intervention groups**1****Description**

Intervention group: Calcium, 1000 mg orally tablets
,twice a day for 2 months, intervention group

Category

Treatment - Drugs

2

Description

Intervention group: Vitamin D, 400 mg orally Tablets, twice a day for 2 months

Category

Treatment - Drugs

3

Description

Intervention group: Zinc, 50 mg orally tablets , once daily for 2 months

Category

Treatment - Drugs

4

Description

Intervention group: Magnesium, 75 mmol oral tablet, once a day for 2 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Marzieh Farimani

Street address

Fatemieh Hospital, Pasdaran avenue

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Heydar Tavillani

Street address

Mahdiye Blvd, Hamadan University of Medical Sciences

City

Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamadan 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

Hamadan University of Medical Sciences

Full name of responsible person

Roghaieh Anvari

Position

Resident of Surgical Obstetrics and Gynecology

Other areas of specialty/work

Street address

Fatemieh hospital, pasdaran avenue, Hamadan

City

Hamadan

Postal code

3519638686

Phone

+98 81 1252 0183

Fax

+98 81 1827 7012

Email

R.anvari@umsha.ac.ir

Web page address

www.umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Marzieh Farimani

Position

Obstetric and Gynecology Surgeon

Other areas of specialty/work

Street address

Fatemieh hospital, Pasdaran avenue

City

Hamadan

Postal code

3519638686

Phone

+98 81 1827 7012

Fax

+98 81 1827 7012

Email

M.Farimanie@umsha.ac.ir

Web page address

www.umsha.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University Medicine of Sciences

Full name of responsible person

Roghaieh Anvari

Position

Resident of Surgical Obstetrics and Gynecology

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

Fatemieh Hospital, pasdaran avenue

City

Hamedan

Postal code

3519638686

Phone

+98 81 1827 7013

Fax

+98 81 1827 7012

Email

R.Anvari@umsha.ac.ir

Web page address

www.umsha.ac.ir

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