

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of the Folic Acid and Vitamin B12 Supplements with Metformin on the Plasma Homocysteine Levels in Women with Polycystic Ovary Syndrome

Protocol summary

Summary

Polycystic ovary syndrome (PCOs) is a common endocrine disorder in the reproductive age. It involves hyperandrogenism, ovulatory disturbances, infertility, obesity, hyperinsulinemia, insulin resistance and cardiovascular diseases (CVD). Metformin is one of the most common prescribed oral drugs for patients with PCOs that sensitize body to insulin. Moreover, Metformin induces increase in homocysteine (Hcy) levels, as an independent risk factor for CVD, by reducing of the plasma vitamin B12 or folate levels. This study is designed to examine the effects of metformin therapy and the folic acid and vitamin B12 supplements on the serum Hcy levels and other cardiovascular factors such as lipid profile and insulin resistance, in patients with PCOs. A total of 150 PCOs patients are selected by using Rotterdam criteria for PCOs (2003) and inclusion and exclusion criteria. Subjects are randomly divided to three groups. The first group receives metformin; the second group receives metformin with vitamin B12 supplement; the third group receives metformin with folic acid supplement, each for 6 months. Process including: Collection of the blood samples (12 h fasting state), measurement of the serum Hcy levels, vitamin B12 and folic acid levels, before and after treatment. Measurement of lipid profile [total cholesterol, HDL-C, LDL-C and triglyceride (TG)], Hormonal parameters [FSH, LH, total testosterone, free testosterone, dehydroepiandrosterone sulphate (DHEAS), 17-OH-progesterone and prolactin], fasting plasma insulin levels, fasting plasma glucose levels and insulin resistance (according to QUICKI and HOMA).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108171760N14**
Registration date: **2012-07-14, 1391/04/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-14, 1391/04/24

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health
Research Center, Babol University of Medical
Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3236 2282

Email address

zahra@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and technology, Babol
University of Medical Sciences

Expected recruitment start date

2011-08-23, 1390/06/01

Expected recruitment end date

2012-08-22, 1391/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the Folic Acid and Vitamin B12 Supplements with Metformin on the Plasma Homocysteine Levels in Women with Polycystic Ovary Syndrome

Public title

Effect of the Folic Acid and Vitamin B12 Supplements with Metformin on the Plasma Homocysteine Levels in Women with Polycystic Ovary Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with PCOs aged 17-35 years. Exclusion criteria: Patients with each background of malady (such as, cardiovascular diseases, diabetes, congenital adrenal hyperplasia,...); using of drugs anti-pregnancy, hormonal, anti-overweight and medications known to interfere with folic acid and vitamin B12 metabolism (such as, metotrexat, nitric oxide and Azaribine), history of hypertension, high activity of body, alcoholic, smoker and subjects with > 120 mg/ml serum folic acid and ≥ 1000 pg/ml vitamin B12 than normal ranges.

Age

From **17 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical sciences, Ganjafroz Avenue

City

Babol

Postal code**Approval date**

2011-08-13, 1390/05/22

Ethics committee reference number

4419/30/پ/ز

Health conditions studied**1****Description of health condition studied**

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

hyperhomocysteinaemia

Timepoint

During the period of six months after treatment

Method of measurement

clinical and laboratory findings

2**Description**

hyperinsulinaemia

Timepoint

During the period of six months after treatment

Method of measurement

clinical and laboratory findings

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

serum folic acid levels

Timepoint

Six months after starting treatment.

Method of measurement

laboratory findings

2**Description**

serum vitamin B12 levels

Timepoint

Six months after starting treatment.

Method of measurement

laboratory findings

3**Description**

serum homocysteine(HCY) levels

Timepoint

Six months after starting treatment.

Method of measurement

laboratory findings

Intervention groups

1

Description

Control group(1): Treated with metformin tablets (500 mg twice daily).Treated for 6 months.

Category

Treatment - Drugs

2

Description

Intervention: group(2):Treated with metformin tablets (500 mg twice daily) with supplements of vitamin B12 (1000 micrograms weekly injections), will be treated for 6 months.

Category

Treatment - Drugs

3

Description

Intervention: group(3):Treated with metformin tablets (500 mg twice daily) with folic acid supplements (1 mg daily), will be treated for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemehzahra Fertility & infertility hospital

Full name of responsible person

Maryam GHolinejad Chari

Street address

Fatemehzahra Fertility & reproductive Health Research Center, Noshirvani street

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

Street address

Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Ganjafroz Avenue

City

Babol

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 and Technology, Babol 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

Fatemehzahra Fertility & reproductive Health Research Center

Full name of responsible person

Nargess Gholizadeh Pasha

Position

M.A/responsible of Reseach Center

Other areas of specialty/work

Street address

Fatemehzahra Fertility & reproductive Health Research Center - noshirvani street

City

Babol

Postal code

Phone

+98 11 1227 4881

Fax

Email

ngh_pa@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Fatemehzahra Fertility & reproductive Health Research Center

Full name of responsible person

Seddigheh Esmaeilzadeh

Position

Gynecologist

Other areas of specialty/work

Street address

Fatemehzahra Fertility & reproductive Health Research, Noshirvani street

City

Babol

Postal code
Phone
+98 11 1227 4881
Fax
Email
sesmael@yahoo.com
Web page address

Postal code
Phone
+98 11 1227 4881
Fax
Email
ngh_pa@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Fatemehzahra Fertility & reproductive Health
Research Center

Full name of responsible person
Nargess Gholizadeh Pasha

Position
M.A/responsible of Reseach Center

Other areas of specialty/work

Street address
Fatemehzahra Fertility & reproductive Health
Research Center - noshirvani street

City
Babol

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