Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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+98 11 3236 2282

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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, metotreksat, 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/ژ/پ

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

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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

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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

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

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Seddigheh Esmaeilzadeh

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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