

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effects of folic acid supplementation on nitric oxide, factors of lipid peroxidation and biomarkers of oxidative stress in overweight and obese women with polycystic ovary syndrome

Protocol summary

Summary

Objective: The aim of this study is to determine the effects of folic acid supplementation on nitric oxide, factors of lipid peroxidation and biomarkers of oxidative stress in overweight women with polycystic ovary syndrome (PCOS). Study design: parallel double-blind randomized controlled clinical trial. Inclusion and Exclusion Criteria: Women aged 18-35 years with overweight diagnosed with PCOS will be included in this study. Individuals with neoplastic, cardiovascular disorders, malabsorptive disorders, current or previous (within the last 6 months) use of hormonal, antidiabetic medications and anti-obesity medications will be excluded in the study. Population and sample size: 75 women with PCOS eligible and referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected. Intervention: Patients will be assigned to receive either 1 mg folic acid supplement (intervention group: n=25), 5 mg folic acid supplement (intervention group: n=25) or placebo (control group: n=25). Fasting blood samples will be taken at baseline and after 8-wk intervention to measure metabolic profiles and inflammatory factor. Start and End Date of Intervention: 8 weeks (November 20, 2013-Jonvier 20, 2014). Outcomes: Baseline and End-of-trial nitric oxide (NO), Malondialdehyde (MDA), total antioxidant capacity (TAC) and glutathione (GSH) levels.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311205623N12**
Registration date: **2013-12-01, 1392/09/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-01, 1392/09/10

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2013-11-20, 1392/08/29

Expected recruitment end date

2014-01-19, 1392/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of folic acid supplementation on nitric oxide, factors of lipid peroxidation and biomarkers of oxidative stress in overweight and obese women with polycystic ovary syndrome

Public title

Effect of supplementation in treatment of polycystic

ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Women aged 18-35 years; diagnosed with PCOS. Exclusion Criteria: Individuals with neoplastic; cardiovascular disorders; malabsorptive disorders; current or previous (within the last 6 months) use of hormonal; antidiabetic medications; anti-obesity medications.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

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

Kashan University of Medical Sciences

Street address

Bolvare Ghotbe Ravandi, Kashan

City

Kashan

Postal code

Approval date

2013-11-20, 1392/08/29

Ethics committee reference number

3461/1/5/29/P

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes

1

Description

Nitric oxide

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

2

Description

Malondialdehyde

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

3

Description

Total Antioxidant Capacity

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

4

Description

Total glutathione

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

5

Description

Catalase

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Folic acid tablet, 1 mg, daily, for 8 weeks orally.

Category

Treatment - Drugs

2

Description

Intervention group: Folic acid tablet, 5 mg, daily, for 8 weeks orally.

Category

Treatment - Drugs

3

Description

Control group: Placebo tablet, daily, for 8 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi Clinic

Full name of responsible person

Zatollah Asemi

Street address

Shahid Rajaei Avenue, Kashan

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Street address

Bolvare Ghotbe Ravandi, Kashan

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Nutrition PhD

Other areas of specialty/work

Street address

Bolvare Ghotbe Ravandi, Kashan

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Email

asemi_z@kaums.ac.ir
asemi_r@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Zatollah Asemi

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

00

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