# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Effects of folic acid supplementation on insulin resistance and inflammatory factor in overweight women with polycystic ovary syndrome

## Protocol summary

**Study aim**

Objective: The aim of this study is to determine the effects of folic acid supplementation on insulin resistance and inflammatory factor in overweight women with polycystic ovary syndrome (PCOS).

**Design**

Study design: Parallel double-blind (both patients and researchers) clinical trial. Randomization will be done by the use of computer-generated random numbers.

**Settings and conduct**

Population and sample size: Among patients with PCOS referred to Emam Reza and Taleghani Clinics affiliated to Arak University of Medical Sciences and Naghavi Clinic affiliated to Kashan University of Medical Sciences, 81 patients will be selected according to inclusion and eclusion criteria.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Women aged 18-40 years diagnosed with PCOS. Exclusion criteria:Women aged<18 or >40 years, those with BMI<25 kg/m2, individuals with neoplastic, hepatic, renal and cardiovascular disorders, malabsorptive disorders, current or previous (within the last 6 months) use of hormonal, antidiabetic medications, anti-obesity medications, intention to adopt a diet and/or a specific physical activity program.

**Intervention groups**

Intervention: Patients will be assigned to receive either 1 mg folic acid supplement (intervention group: n=27), 5 mg folic acid supplement (intervention group: n=27) or placebo (control group: n=27).

**Main outcome variables**

Outcomes: Markers of insulin metabolism and hormonal profiles (primary outcomes) and lipid profiles, biomarkers of inflammation and oxidative stress (secondary outcome) will be quantified at study baseline and end-of-trial.

## General information

**Reason for update**

Due to an error, the request for an update in our website was conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201306085623N8**
Registration date: **2013-06-20, 1392/03/30**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-31, 1398/08/09**
Update count: **1**

**Registration date**

2013-06-20, 1392/03/30

**Registrant information**

**Name**
Zatollah Asemi
**Name of organization / entity**
Kashan University of Medical Sciences
**Country**
Iran (Islamic Republic of)
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**Recruitment status**

**Recruitment complete**

**Funding source**

Arak University of Medical Sciences

**Expected recruitment start date**

2013-06-04, 1392/03/14

**Expected recruitment end date**

2013-07-04, 1392/04/13

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effects of folic acid supplementation on insulin resistance and inflammatory factor in overweight 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 18-40 years diagnosed with PCOS

**Exclusion criteria:**

Women aged<18 or >40 years Those with BMI<25 kg/m2, individuals with neoplastic, hepatic, renal and cardiovascular disorders Malabsorptive disorders Current or previous (within the last 6 months) use of hormonal Antidiabetic medications Anti-obesity medications Intention to adopt a diet and/or a specific physical activity program

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **81**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take folate 1 mg (n=27), folate 5 mg (n=27) and placebo (n=27). Randomization will be done by the use of computer-generated random numbers.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Arak University of Medical Sciences

**Street address**

Vice-chancellor for Education and Research, Sardasht Avenue, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3814113634

**Approval date**

2013-06-03, 1392/03/13

**Ethics committee reference number**

92-147-9

## 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**

Insulin

**Timepoint**

At the beginning of the study and after 8 weeks of intervention

**Method of measurement**

Elisa

### 2

**Description**

Hs-CRP

**Timepoint**

At the beginning of the study and after 8 weeks of intervention

**Method of measurement**

Elisa

## Secondary outcomes

**1**

**Description**
Insulin resistance
**Timepoint**
At the beginning of the study and after 8 weeks of intervention
**Method of measurement**
Questionnaire

**2**

**Description**
Triglycerides
**Timepoint**
At the beginning of the study and after 8 weeks of intervention
**Method of measurement**
Enzymatic kit

**3**

**Description**
Total cholesterol
**Timepoint**
At the beginning of the study and after 8 weeks of intervention
**Method of measurement**
Enzymatic kit

**4**

**Description**
HDL
**Timepoint**
At the beginning of the study and after 8 weeks of intervention
**Method of measurement**
Enzymatic kit

**5**

**Description**
VLDL
**Timepoint**
At the beginning of the study and after 8 weeks of intervention
**Method of measurement**
Enzymatic kit

**6**

**Description**
LDL
**Timepoint**
At the beginning of the study and after 8 weeks of intervention
**Method of measurement**
Enzymatic kit

**7**

**Description**
FPG
**Timepoint**
At the beginning of the study and after 8 weeks of intervention
**Method of measurement**
Enzymatic kit

**8**

**Description**
Total antioxidant
**Timepoint**
At the beginning of the study and after 8 weeks of intervention
**Method of measurement**
Spectrophotometry

**9**

**Description**
Glutathione
**Timepoint**
At the beginning of the study and after 8 weeks of intervention
**Method of measurement**
Spectrophotometry

**10**

**Description**
Malondialdehyde
**Timepoint**
At the beginning of the study and after 8 weeks of intervention
**Method of measurement**
Spectrophotometry

**11**

**Description**
Nitric oxide
**Timepoint**
At the beginning of the study and after 8 weeks of intervention
**Method of measurement**
Spectrophotometry

**12**

**Description**
Catalase
**Timepoint**
At the beginning of the study and after 8 weeks of intervention
**Method of measurement**
Spectrophotometry

## 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**
Emam Reza and Taleghani Clinics
**Full name of responsible person**
Maryam Karamali
**Street address**
Emam Khomeyni Avenue, Arak
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**Postal code**
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+98 86 3223 3823
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karamali.maryam2@gmail.com

**2**

**Recruitment center**
**Name of recruitment center**
Naghavi Clinic
**Full name of responsible person**
Zatollah Asemi
**Street address**
Shahid Rajaee Avenue, Kashan
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asemi_z@kaums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Arak University of Medical Sciences
**Full name of responsible person**
Mohammad Rafiee
**Street address**
Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Vice chancellor for research, Arak University of Medical Sciences
**Proportion provided by this source**
50
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

**2**

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Kashan University of Medical Sciences
**Full name of responsible person**
Gholamali Hamidi
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Ghotbe Ravandi Boulevard, Kashan
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**Email**

Gholamali_h@kaums.ac.ir

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Vice chancellor for research, Kashan University of Medical Sciences

**Proportion provided by this source**

50

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Zatollah Asemi

**Full name of responsible person**

Kashan University of Medical Sciences

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for scientific inquiries

**Contact**

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**Other areas of specialty/work**

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**Contact**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to

| | |
|---|---|
| make this available | |
| **Data Dictionary** | Undecided - It is not yet known if there will be a plan to make this available |