

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 exclusion 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/m<sup>2</sup>, 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)

##### Phone

+98 36 1534 3570

##### Email address

asemi\_z@kaums.ac.ir

##### 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/m<sup>2</sup>, 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

#### City

Arak

#### Province

Markazi

#### Postal code

3814113634

#### Phone

+98 86 3223 3823

#### Email

karamali.maryam2@gmail.com

## 2

### Recruitment center

#### Name of recruitment center

Naghavi Clinic

#### Full name of responsible person

Zatollah Asemi

#### Street address

Shahid Rajaei Avenue, Kashan

#### City

Kashan

#### Province

Isfahan

#### Postal code

1771844351

#### Phone

+98 31 5546 3378

#### Email

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

#### City

Arak

#### Province

Markazi

#### Postal code

3814113634

#### Phone

+98 86 3223 3823

#### Email

rafiee-m@aums.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, 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

#### Street address

Ghotbe Ravandi Boulevard, Kashan

#### City

Kashan

#### Province

Isfahan

#### Postal code

1771844351

#### Phone

+98 31 5546 3378

#### 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

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

1771844351

**Phone**

+98 31 5546 3378

**Email**

asemi\_z@kaums.ac.ir

**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

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

1771844351

**Phone**

+98 36 1446 3378

**Fax**

+98 31 5546 3378

**Email**

asemi\_r@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Zatollah Asemi

**Position**

Nutrition PhD

**Latest degree**

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1771844351

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+98 31 5546 3378

**Fax**

**Email**

asemi\_r@yahoo.com

**Web page address**

**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