

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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/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)

Phone

+98 36 1534 3570

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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

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Emam Khomeyni Avenue, Arak

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2**Recruitment center****Name of recruitment center**

Naghavi Clinic

Full name of responsible person

Zatollah Asemi

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Isfahan

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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

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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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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

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Latest degree

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Position

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Latest degree

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Other areas of specialty/work

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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