Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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)
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/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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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 Rajaee Avenue, Kashan
City
Kashan
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Isfehan
Postal code
1771844351
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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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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
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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

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Full name of responsible person

Zatollah Asemi

Position

Nutrition PhD

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Zatollah Asemi

Position

Nutrition PhD

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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