

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of the hypocaloric DASH diet on metabolic parameters, inflammatory factor and biomarkers of oxidative stress in overweight and obese women with polycystic ovary syndrome

#### Protocol summary

##### Study aim

The aim of this study is to determine the effects of the Dietary Approaches to Stop Hypertension (DASH) diet on metabolic profiles, inflammatory factor and biomarkers of oxidative stress in overweight and obese women with polycystic ovary syndrome (PCOS).

##### Design

Study design: parallel single-blind randomized controlled clinical trial.

##### Settings and conduct

Among patients with PCOS referred to Naghavi outpatient Clinic affiliated to Kashan University of Medical Sciences, 108 patients will be selected according to inclusion and exclusion criteria. Participants are unaware of the study groups. Fasting blood samples will be taken at baseline and 8 weeks after the intervention. At the beginning and the end of the intervention: 8 weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion and Exclusion Criteria: Women aged 18-40 years with overweight and obese 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.

##### Intervention groups

Intervention: Patients will be assigned to receive either the DASH diet (intervention group 1: n=27) or the standard diet (control group 1: n=27) and the DASH diet (intervention group 2: n=27) or the standard diet (control group 2: n=27).

##### Main outcome variables

Outcomes: Hs-CRP and LDL-cholesterol (primary outcomes) and glycemic control, other lipid profiles, biomarkers of inflammation and oxidative stress (secondary outcomes) will be quantified at study

baseline and end-of-trial

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201304235623N6**

Registration date: **2013-05-04, 1392/02/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-08-11, 1398/05/20**

Update count: **1**

##### Registration date

2013-05-04, 1392/02/14

##### 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

2013-04-23, 1392/02/03

##### Expected recruitment end date

2013-06-18, 1392/03/28

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effects of the hypocaloric DASH diet on metabolic parameters, inflammatory factor and biomarkers of oxidative stress in overweight and obese women with polycystic ovary syndrome

**Public title**

Effect of diet therapy in treatment of polycystic ovary syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women aged 18-40 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 **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **108**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

At first, patients were randomly allocated into two groups to take either DASH diet or control. Randomization will be done by the use of computer-generated random numbers.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants are unaware of the study groups.

**Placebo**

Not 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

**Province**

Isfahan

**Postal code**

8115187159

**Approval date**

2013-04-23, 1392/02/03

**Ethics committee reference number**

P/29/5/1/9213

**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**

LDL-Cholesterol

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Enzymatic

**2****Description**

hs-CRP

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Elisa

**Secondary outcomes****1****Description**

Triglycerides

**Timepoint**

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

**Method of measurement**

Enzymatic kit

**2****Description**

HDL-cholesterol

**Timepoint**

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

**Method of measurement**

Enzymatic kit

**3**

**Description**

Insulin

**Timepoint**

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

**Method of measurement**

Elisa kit

**4**

**Description**

Insulin resistance

**Timepoint**

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

**Method of measurement**

Calculation using HOMA formula

**5**

**Description**

Total antioxidant capacity

**Timepoint**

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

**Method of measurement**

Spectrophotometry

**6**

**Description**

**Timepoint**

**Method of measurement**

**7**

**Description**

Glutathione

**Timepoint**

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

**Method of measurement**

Spectrophotometry

**Intervention groups**

**1**

**Description**

Control group: Standard diet designed based on calorie-restricted (500 kcal), 3 serving vegetables, 3 serving fruits, rich in protein, daily for 8 weeks

**Category**

Other

**2**

**Description**

Intervention group: DASH diet designed based on calorie-restricted (500 kcal), 5 serving vegetables, 5 serving fruits, rich in fiber and whole grains, daily for 8 weeks

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Naghavi Clinic

**Full name of responsible person**

Zatollah Asemi

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Shahid Rajaei Avenue, Kashan

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**Sponsors / Funding sources**

**1**

**Sponsor**

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**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**

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**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Zatollah Asemi  
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PhD of Nutrition  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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