Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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
Isfehan
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 Rajaee Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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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

Position

PhD of Nutrition

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