Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effects of Dietary Approaches to Stop Hypertension (DASH) diet on hormonal profiles in patients with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study is to determine the effects of Dietary Approaches to Stop Hypertension diet on hormonal profiles in patients with polycystic ovary syndrome.

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: 60 patients with PCOS of eligible and referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCOS according to Rotterdam criteria aged 18 to 40 years. Exclusion criteria: Pregnant during the intervention, hyperplasia, androgen-secreting tumors, hyperprolactinemia, thyroid dysfunction, diabetes or impaired glucose tolerance.

Intervention groups

Intervention: Patients will be assigned to receive either low-calorie DASH (intervention group: n=30) or normal diet (control group: n=30). Fasting blood samples will be taken at baseline and after 12-wk intervention. Start and end date of intervention: 3 months.

Main outcome variables

Outcomes: Anti-Mullerian Hormone (AMH) (primary outcome) and markers of insulin metabolism, hormonal profiles, nitric oxide and malondialdehyde (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: **IRCT201601055623N66**
Registration date: **2016-01-11, 1394/10/21**
Registration timing: **retrospective**

Last update: **2019-11-06, 1398/08/15**
Update count: **1**

Registration date

2016-01-11, 1394/10/21

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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+98 36 1534 3570

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2015-12-23, 1394/10/02

Expected recruitment end date

2016-01-04, 1394/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effects of Dietary Approaches to Stop Hypertension (DASH) diet on hormonal profiles in patients with polycystic ovary syndrome

Public title
Effect of diet therapy in treatment of women with polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with PCOS according to Rotterdam criteria Aged 18 to 40 years
Exclusion criteria:
Pregnant during the intervention Hyperplasia Androgen secreting tumors Hyperprolactinemia Thyroid dysfunction Diabetes or impaired glucose tolerance
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
At study baseline and after stratification on pre-intervention BMI (25-29.9 and ≥30 kg/m2) and age (<40 and ≥40 y), subjects will be randomly divided into two groups to receive either low-calorie DASH (n = 30) or placebo (n = 30). 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
Ethics committee of Kashan University of Medical Sciences
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Approval date
2015-12-22, 1394/10/01
Ethics committee reference number
IR.Kaums.REC.1394.130

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Anti-Mullerian Hormone
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

Secondary outcomes

1

Description
Follicular-stimulating hormone
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

2

Description
Testosterone
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

3

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

4

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

5

Description
Insulin resistance
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

6

Description
Fasting blood sugar
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

7

Description
Insulin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

8

Description
LH
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

9

Description
SHBG
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

Intervention groups

1

Description
Intervention group: DASH diet, 6 serving vegetables, 6 serving fruits, rich in fiber and whole grains, daily for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: Standard diet, 4 serving vegetables, 4 serving fruits, rich in protein, daily for 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
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8115187159
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asemi_r@yahoo.com

Sponsors / Funding sources

1

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
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hamidi_gh@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, 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
Street address
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Person responsible for scientific inquiries

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Web page address

Person responsible for updating data

Contact
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1771844351
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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