

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

asemi_z@kaums.ac.ir

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

Isfahan

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 Rajaei Avenue, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 5545 1515

Email

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

City

Kashan

Province

Isfahan
Postal code
8115187159
Phone
+98 31 5554 0021
Email
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
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfahan
Postal code
1771844351
Phone
+98 31 5546 3378
Email
asemi_z@kaums.ac.ir

Person responsible for scientific 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
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfahan
Postal code
1771844351
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.ac.ir
Web page address

Person responsible for updating data

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
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfahan
Postal code
1771844351
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.ac.ir
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