Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of legume-based DASH diet on anthropometric factors, glucose & lipid profiles and testosterone level in women with polycystic ovary syndrome (PCOS): A randomized clinical trial

Protocol summary

Study aim
Determining The effects of legume-based DASH diet on anthropometric factors, glucose & lipid profiles and testosterone level in women with polycystic ovary syndrome (PCOS)

Design
Randomized clinical trial

Settings and conduct
The present study is a randomized controlled clinical trial to evaluate the effect of legume-based DASH counseling and diet on anthropometric factors, glucose & lipid profiles and testosterone level factors in patients with polycystic ovary syndrome, which is referred to Shahid Sadoughi hospital will be performed in Yazd for 12 weeks. In addition, people with PCOS receive their routine treatment under the supervision of a specialist. Age and BMI is a confounding factor and is eliminated in statistical models. Participation in the study is completely free and is managed by explaining in detail the study process, goals, benefits and limitations and obtaining written and oral consent with the patient's signature.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Women of reproductive age and before menopause (20-50 years) 2. Women with PCOS according to the Rotterdam criteria 3. Oligomenorrhea or amenorrhea 4. Clinical or laboratory hyperandrogenism Exclusion criteria: 1. Age less than 20 or more than 50 years 2. Pregnancy, miscarriage or breastfeeding in the last 6 months 3. Oligomenorrhea caused by secondary causes, including endocrine disorders (congenital adrenal hyperplasia, androgen-secreting tumors, Cushing's syndrome, hyperprolactinemia, adrenal disorders) 4. Previous history or current getting with any cancer 5. History of type 2 diabetes 6. Intrauterine Insemination (IUI) or In Vitro Fertilization(IVF) 7. Special diets or low-calorie diets in the past three months, including vegetarian diets

Intervention groups
legume-based DASH diet recipient group

Main outcome variables
Anthropometric factors, glucose & lipid profiles and testosterone

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120913010826N33**
Registration date: **2023-06-12, 1402/03/22**
Registration timing: **prospective**

Last update: **2024-08-22, 1403/06/01**
Update count: **1**

Registration date
2023-06-12, 1402/03/22

Registrant information

Name
Azadeh Nadjarzadeh

Name of organization / entity
Shahid Sadoughi University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-20, 1402/03/30

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of legume-based DASH diet on anthropometric factors, glucose & lipid profiles and testosterone level in women with polycystic ovary syndrome (PCOS): A randomized clinical trial

Public title
Effect of legume-based DASH diet in patients with polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women of reproductive age and before menopause (20-50 years) Women with PCOS according to the Rotterdam criteria Oligomenorrhea or amenorrhea Clinical or laboratory hyperandrogenism
Exclusion criteria:
Pregnancy, miscarriage or breastfeeding in the last 6 months Oligomenorrhea caused by secondary causes, including endocrine disorders (congenital adrenal hyperplasia, androgen-secreting tumors, Cushing's syndrome, hyperprolactinemia, adrenal disorders) Previous history or current getting with any cancer History of type 2 diabetes Intrauterine Insemination (IUI) or In Vitro Fertilization) IVF(Special diets or low-calorie diets in the past three months, including vegetarian diets

Age
From **20 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
The stratified randomization method is used for random allocation. Therefore, we first classify BMI into three groups: standard, overweight, and obese, and then use a simple random assignment method in each group. First, eligible people are classified into BMI groups, and then in each BMI group, the first eligible person is number 1 and the next person is number 2, and so on until the 27th person. Random Allocation software version 1 is used to prepare the random allocation list.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The term "legumes" includes legumes, soybeans, peas, beans, etc.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of School of Public Health, Shahid Sadoughi University of Medical Sciences,

Street address
Shohaday-e-Gomnam Blvd., Alem Sq., Yazd, Iran

City
Yazd

Province
Yazd

Postal code
8915173160

Approval date
2023-05-28, 1402/03/07

Ethics committee reference number
IR.SSU.SPH.REC.1402.018

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
HOMA-IR index

Timepoint
Before intervention and 16 weeks after intervention

Method of measurement
HOMA-IR = (Glu ×Insulin)/405

2

Description
Low density lipoprotein cholesterol (LDL)

Timepoint
Before intervention and 16 weeks after intervention

Method of measurement
Special kit

3

Description
High density lipoprotein cholesterol (HDL)
Timepoint
Before intervention and 16 weeks after intervention
Method of measurement
Special kit

4

Description
Triglyceride
Timepoint
Before intervention and 16 weeks after intervention
Method of measurement
Special kit

5

Description
Total cholesterol
Timepoint
Before intervention and 16 weeks after intervention
Method of measurement
Special kit

6

Description
FBS
Timepoint
Before intervention and 16 weeks after intervention
Method of measurement
Special kit

7

Description
Serum insulin
Timepoint
Before intervention and 16 weeks after intervention
Method of measurement
Special kit

8

Description
Free testosterone
Timepoint
Before intervention and 16 weeks after intervention
Method of measurement
Special kit

Secondary outcomes

1

Description
Weight, fat mass, fat free mass, RMR, body mass index and visceral fat
Timepoint
Before intervention and 16 weeks after the intervention
Method of measurement
Omron digital Scale

2

Description
Waist,Hip circumference
Timepoint
Before intervention and 16 weeks after the intervention
Method of measurement
Meter

3

Description
Total energy intake, total nutrients intake
Timepoint
Before intervention and 16 weeks after the intervention
Method of measurement
24 hour recall

4

Description
The length of the menstrual cycle
Timepoint
Before intervention and 16 weeks after the intervention
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: Legume-based DASH diet. DASH diet (Dietary Approaches to Stop High Blood Pressure) that contains 50-55% carbohydrates, 15-20% protein and 25-30% fat. The DASH diet is high in fruits, vegetables, whole grains, and low-fat dairy, and low in saturated fat, cholesterol, and refined grains. In the legume-based DASH diet, we replace up to 1 to 3 units of meat and grains with more legumes and soybeans. The calories needed by each patient are estimated based on the basal metabolic rate (using the Harris-Benedict equation) and the levels of physical activity and energy resulting from food metabolism. For people who are overweight or obese, a caloric restriction of 500 to 700 kcal less than the calculated energy requirement for each person is considered. 500 kcal for those whose BMI is in the range of 25-31 kg/m2 and 700 kcal for those with a BMI greater than 31 kg/m2 will be deducted from the total energy needed by each person, and weight loss is intended for these people. The replacement list is provided to the patient while educating the patient to make it easier to choose foods and comply with the principle of diversity between the components of each food group.
Category
Lifestyle

2

Description

Control group: A standard diet that contains 50-55% carbohydrates, 15-20% protein and 25-30% fat. The calories needed by each patient are estimated based on the basal metabolic rate (using the Harris-Benedict equation) and the levels of physical activity and energy resulting from food metabolism. For people who are overweight or obese, a caloric restriction of 500 to 700 kcal less than the energy requirement calculated for each person is considered. 500 kcal for people whose BMI is in the range of 25-31 kg/m2 and for people whose BMI is more than 31 kg/m2, 700 kcal is deducted from the total energy requirement of each person, and weight loss for These people are considered. The replacement list is provided to the patient while educating the patient to make it easier to choose foods and comply with the principle of variety between the components of each food group.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi Hospital, Yazd
Full name of responsible person
Seyed Reza Atashi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Assistant, Yazd 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
Research Assistant, Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Dr Azadeh Najarzadeh
Position
Phd of nutritin
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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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