Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of low-calorie Dietary Approaches to Stop Hypertension diet (DASH) and synbiotic supplement on metabolic risk factors, serum levels of some inflammatory, oxidant factors and antimullerin hormone in women with polycystic ovary syndrome

Protocol summary

Study aim

Determining the combined effect of low-calorie Dietary Approaches to Stop Hypertension diet (DASH) and synbiotic supplement on metabolic risk factors, serum levels of some inflammatory factors, oxidants, and antimullerin hormone in women with polycystic ovary syndrome

Design

The clinical trial has four groups, including three intervention groups and one control group, with parallel, double-blind, randomized, phase 3 groups on 76 patients. A table of random numbers will be used for randomization.

Settings and conduct

This study will be conducted as a double-blind clinical trial on 76 women aged 18 to 45 in Ahvaz for 12 weeks. The study subjects will be randomly allocated in one of the following four groups: 1- receiving low-calorie Dietary Approaches to Stop Hypertension diet (DASH) + synbiotic supplement (500 mg per day) 2- receiving low-calorie DASH diet + placebo 3- receiving standard low-calorie diet + synbiotic supplement (500 mg per day) 4- receiving standard low-calorie diet + placebo (control group) Lack of knowledge of the participants and the examiners of the results of the characteristics of the group of people

Participants/Inclusion and exclusion criteria

Age between 18 and 45 years Body mass index between 27-35 Diagnosis and confirmation of polycystic ovary syndrome by an endocrinologist based on the Rotterdam criteria

Intervention groups

Four studied groups 1- receiving low-calorie Dietary Approaches to Stop Hypertension diet (DASH) + synbiotic supplement (500 mg per day) 2- receiving low-calorie DASH diet + placebo 3- receiving standard low-calorie diet + synbiotic supplement (500 mg per day) 4- receiving standard low-calorie diet + placebo (control group)

Main outcome variables

CRP, HBA1C, GSH, AMH, insulin, leptin, testosterone, fasting glucose, TG, HDL-C, TC, LDL-C, visceral obesity index, insulin resistance, insulin sensitivity, AIP and VAI, malondialdehyde

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230220057464N1**
Registration date: **2023-02-23, 1401/12/04**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-23, 1401/12/04**
Update count: **0**

Registration date

2023-02-23, 1401/12/04

Registrant information

Name

Fatemeh Farahmandpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-02-21, 1401/12/02
Expected recruitment end date
2024-02-21, 1402/12/02
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of low-calorie Dietary Approaches to Stop Hypertension diet (DASH) and synbiotic supplement on metabolic risk factors, serum levels of some inflammatory, oxidant factors and antimullerin hormone in women with polycystic ovary syndrome

Public title
Effect of low-calorie Dietary Approaches to Stop Hypertension diet (DASH) and synbiotic supplement on women with polycystic ovary syndrome
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 45 years Body mass index between 27-35 Diagnosis and confirmation of polycystic ovary syndrome by an endocrinologist based on the Rotterdam criteria Not having conditions such as pregnancy, breastfeeding and menopause Not taking probiotics or synbiotics in the last three months Not suffering from other causes of hyperandrogenism such as congenital adrenal hyperplasia, Cushing's syndrome, ovarian or adrenal tumor Not suffering from hypothyroidism No diabetes
Exclusion criteria:
Reluctance to cooperate Following special diets
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, blocked randomization method will be used. In this method, even-sized blocks are created, and in these blocks, a quarter of the people in each block will be considered as belonging to one of the four groups. Then, among the created blocks, so many blocks are randomly selected to reach the required sample size.
Blinding (investigator's opinion)
Double blinded
Blinding description
People participating in the study will be studied randomly in one of four groups. The supplement and placebo will be given to people with the same appearance and packaging, so that the people under study and the researcher will not know about the contents of the packages. Finally, the person who will do the evaluation of the results will not know how to allocate people.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences
Street address
Nutrition and Metabolic Diseases Research Center, Jundishapur University of Medical Sciences, Ahvaz, Ahvaz. Golestan
City
Ahvaz
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Khouzestan
Postal code
15794 - 61357
Approval date
2023-01-29, 1401/11/09
Ethics committee reference number
IR.AJUMS.REC.1401.484

Health conditions studied

1

Description of health condition studied
Women with polycystic ovary syndrome
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
CRP, HBA1C, GSH, AMH, insulin, leptin and testosterone, fasting glucose, TG, HDL-C, TC, LDL-C, visceral obesity index, insulin resistance, insulin sensitivity, AIP and VAI, malondialdehyde
Timepoint
All outcomes will be measured at the beginning of the study and at the end of the 12 weeks of the study.
Method of measurement

CRP, HBA1C, GSH, AMH, insulin, leptin and testosterone by ELISA method, fasting glucose, TG, HDL-C, TC by photometric method, LDL-C, visceral obesity index, insulin resistance, insulin sensitivity, AIP and VAI They will be measured using the relevant formulas. Malondialdehyde will be measured by TBARS method.

Secondary outcomes

1

Description
Weight, BMI, waist circumference, hip circumference, ratio of waist circumference to hip circumference, hirsutism rate, sleep quality, alopecia rate and appetite rate

Timepoint
The beginning of the study and 12 weeks after the start of the intervention (the end of the study)

Method of measurement
Weight using a scale. BMI using the formula. Waist circumference, hip circumference, ratio of waist circumference to circumference using a meter, amount of hirsutism, quality of sleep, amount of alopecia, and amount of appetite, respectively, using questionnaires of hirsutism, quality of Pittsburgh sleep, alopecia, and appetite.

Intervention groups

1

Description
Intervention group: Intervention group: 1- group receiving low-calorie DASH diet + synbiotic supplement (500 mg per day) 2- group receiving low-calorie DASH diet + placebo 3- group receiving standard low-calorie diet + synbiotic supplement Biotic (500 mg per day) 4- group receiving standard low-calorie diet + placebo (control group)

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrinologist and metabolism doctor's office

Full name of responsible person
Fatemeh Haidari

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Nutrition and Metabolic Diseases Research Center, Jundishapur University of Medical Sciences, Ahvaz, Ahvaz. Golestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mehrnoosh Zakerkish

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Ahvaz Academic City - Vice-Chancellor for Research and Technology, Jundishapur University of Medical Sciences and Healthcare Services, Ahvaz - ground floor

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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
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Fatemeh Farahmandpour

Position
Phd student

Latest degree
Master

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