

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 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)

Phone

+98 61 3311 0000

Email address

farahmand901@gmail.com

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 science

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

Province

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.

15794 - 61357

Phone

+98 61 3311 0000

Email

farahmand901@gmail.com

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

Street address

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

City

Ahvaz

Province

Khuzestan

Postal code

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Street address

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

City

Ahvaz

Province

Khuzestan

Postal code

15794 - 61357

Phone

+98 61 3336 2414

Email

itc@ajums.ac.ir

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

Street address

Ahvaz, Golestan, Jundishapur University of Medical Sciences, Ahvaz- Faculty of Paramedicine, Nutrition Research Center

City

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Phone

+98 61 3311 0000

Fax**Email**

farahmand901@gmail.com

Person responsible for scientific 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

Street address

Ahvaz, Golestan, Jundishapur University of Medical Sciences, Ahvaz- Faculty of Paramedicine, Nutrition Research Center

City

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Phone

+98 61 3311 0000

Fax**Email**

farahmand901@gmail.com

Person responsible for updating data**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

Street address

Ahvaz, Golestan, Jundishapur University of Medical Sciences, Ahvaz- Faculty of Paramedicine, Nutrition Research Center

City

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Phone

+98 61 3311 0000

Fax**Email**

farahmand901@gmail.com

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