Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The Effect of Yoghurt Fortified with Probiotics and Vitamins D and E on Anthropometric and Biochemical Indices, Blood Pressure, Sleep Quality, and Mental Health in Patients with Polycystic Ovary Syndrome: A Randomized, Double-Blind, Controlled Clinical Trial

Protocol summary

Study aim

The effect of yogurt fortified with probiotics, vitamin D and vitamin E on anthropometric indices, biochemical indices, blood pressure, sleep quality and mental health in patients with polycystic ovary syndrome.

Design

This clinical trial is randomized, double-blind, placebo-controlled and parallel in phase 3, on 90 eligible people. Ninety people are allocated between two groups by block randomization method (45 people in each group).

Settings and conduct

Patients referred to Shiraz Mother and Child Hospital after knowing about the study, if they agree and obtain written and informed consent, are randomly assigned to 2 study groups (using the block randomization method). The participants receive the yogurts corresponding to their group, which are named in line with the names of the groups with letters A and B for the blinding of the participant and the researcher, and consume them daily before meals for 8 weeks. Evaluation of anthropometric and biochemical indicators, and completion of mental health and sleep quality questionnaires are done before and after the study.

Participants/Inclusion and exclusion criteria

Exclusion criteria: Women with polycystic ovary syndrome between the ages of 18 and 45 who are not breastfeeding or pregnant. Inclusion criteria: have no history of chronic diseases and have not taken antibiotics and nutritional supplements for 3 months before entering the study.

Intervention groups

1- Intervention group: 8 weeks of intaking120 grams per day of low-fat yogurt containing vitamin D (with a dose of 1000 IU or 25 micrograms), vitamin E (with a dose of 50 IU or 34 mg) and probiotics (Bifidobacterium animalis BB12 and Lactobacillus Acidophilus LA-5 in a dose of at least 10^6 CFU/gr) 2- Placebo group: 8 weeks of intaking120 grams per day of plain low-fat yogurt as a placebo

Main outcome variables

HOMA-IR

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231210060323N1**
Registration date: **2023-12-14, 1402/09/23**
Registration timing: **prospective**

Last update: **2023-12-19, 1402/09/28**
Update count: **1**

Registration date

2023-12-14, 1402/09/23

Registrant information

Name

Moein Askarpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 1001

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date
2024-07-20, 1403/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Yoghurt Fortified with Probiotics and Vitamins D and E on Anthropometric and Biochemical Indices, Blood Pressure, Sleep Quality, and Mental Health in Patients with Polycystic Ovary Syndrome: A Randomized, Double-Blind, Controlled Clinical Trial

Public title
Effect of Yoghurt Fortified with Probiotics and Vitamins D and E in Treatment of Polycystic Ovary Syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to cooperate in the study and provide written consent Being in the reproductive age range of 18-45 years Diagnosis of polycystic ovary syndrome based on the Rotterdam criteria No intake of alcohol or drugs Not pregnant or breastfeeding No menopause No participate in other research studies
Exclusion criteria:
Using drugs affecting blood pressure, blood lipids, ovarian function, insulin sensitivity (including metformin, incretin, and Thiazolidinediones) and oral contraceptives (including progesterone and estrogen) since 3 months before entering the study. Taking any nutritional supplements for 3 months before entering the study Taking drugs affecting vitamin D metabolism having diabetes, thyroid disease or any systemic disease (such as kidney, liver, digestive system, cardiovascular system) Having disorders that lead to an increase in androgens in the blood (such as Cushing's syndrome, hyperprolactinemia)
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned using random blocks (ratio 1:1) for two groups (a control group and an intervention group). In this way, the double blocks will be created by someone outside the study. Then, a block is randomly selected to determine the assigned groups for the first two participants. In order to blind the researchers of this project, the assigned group will be placed in sealed envelopes by a person other than the researcher and a person outside the study, and in this way the allocation will be concealed. During the study, as each participant enters the study, according to the order, an envelope is opened and the assigned group is determined.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to blind the interventions, fortified yogurts (including two types of intervention yogurt and low-fat conventional yogurt) will be provided to people in deposable containers with the same color, smell, taste and appearance, which will be named with the letters A and B. The process of filling the yogurt containers and naming them will be done by someone outside the study, and the members of the research team and the participants of the different groups will be unaware of the type of intervention and the type of yogurt they received, so that the principles for blinding will be accomplished.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee in research of the faculties of health, nutrition and food sciences-Shiraz Universi
Street address
Faculty of Health, Nutrition and Food Sciences, Razi Boulevard, Shiraz
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2023-10-22, 1402/07/30
Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1402.104

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

Homeostasis model assessment of insulin resistance

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

Formula

Secondary outcomes

1

Description

Weight

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

Scale

2

Description

Body Mass Index

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

Formula

3

Description

Waist Circumference

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

Stadiometer

4

Description

Hip Circumference

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

Stadiometer

5

Description

Waist to Hip Ratio

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

Formula

6

Description

Systolic Blood Pressure

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

Electronic Sphygmomanometer

7

Description

Diastolic Blood Pressure

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

Electronic Sphygmomanometer

8

Description

Fasting Blood Sugar

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

Pars Azmoon Kit

9

Description

Fasting Insulin

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

ELISA Kit

10

Description

The Quantitative Insulin Sensitivity Check Index

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

Formula

11

Description
Total Cholesterol
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)
Method of measurement
Pars Azmoon Kit

12

Description
Triglyceride
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)
Method of measurement
Pars Azmoon Kit

13

Description
Low-Density Lipoprotein Cholesterol
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)
Method of measurement
Pars Azmoon Kit

14

Description
High-Density Lipoprotein Cholesterol
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)
Method of measurement
Pars Azmoon Kit

15

Description
Total Testosterone
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)
Method of measurement
ELISA Kit

16

Description
Sex Hormone Binding Globulin
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)
Method of measurement
ELISA Kit

17

Description
Dehydroepiandrosterone Sulfate
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)
Method of measurement
ELISA Kit

18

Description
Luteinizing Hormone
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)
Method of measurement
Pars Azmoon Kit

19

Description
Follicle-Stimulating Hormone
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)
Method of measurement
Pars Azmoon Kit

20

Description
Free Androgen Index
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)
Method of measurement
Formula

21

Description
High-Sensitivity C-Reactive Protein
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)
Method of measurement
ELISA Kit

22

Description

Malondialdehyde

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

Spectrophotometry

23

Description

Total Antioxidant Capacity

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

Spectrophotometry

24

Description

Mental Health

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

The Depression, Anxiety and Stress Scale - 21 Items Questioner

25

Description

Quality of Sleep

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

Pittsburgh Sleep Quality Index

26

Description

Body Fat Percentage

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

Body Composition Analyzer

27

Description

Skeletal Muscle Mass

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (8 weeks after the start of the intervention)

Method of measurement

Body Composition Analyzer

Intervention groups

1

Description

Intervention group: Intaking120 grams per day of low-fat yogurt containing vitamin D (with a dose of 1000 IU or 25 micrograms) and vitamin E (with a dose of 50 IU or 34 mg) and two probiotic strains of lactobacillus (Lactobacillus acidophilus LA5) and bifidobacterium (Bifidobacterium animalis BB12) at least 10^6 cfu/g for 8 weeks

Category

Treatment - Other

2

Description

Control group: Intaking120 grams per day of conventional low-fat yogurt for 8 weeks as a placebo

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Ghadir Mother and Child Hospital, Infertility Clinic

Full name of responsible person

Bahia Namavar Jahromi

Street address

The beginning of Golshan town, Imam Reza Boulevard,

City

Shiraz

Province

Fars

Postal code

7144995377

Phone

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Email

enghelab@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Najmeh Hejazi

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Province

Fars

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Phone
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Email
najmehhejazi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Moein Askarpour
Position
PhD student
Latest degree
Master
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
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Latest degree
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Other areas of specialty/work
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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