Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effects of synbiotic supplement containing Bacillus coagulans on glycemic control, lipid profile, testosterone, systemic inflammation and anthropometric measurements in women with polycystic ovarian syndrome.

Protocol summary

Study aim
determining the effects of synbiotic supplement containing Bacillus coagulans on glycemic control, lipid profile, testosterone, inflammation and anthropometric measurements in women with polycystic ovarian syndrome (PCOS).

Design
Two arm parallel group randomised trial, triple blind, phase 3 and on 50 women with PCOS. For randomization, the Stratified Blocked Randomization method will be used.

Settings and conduct
Individuals with polycystic ovary syndrome referred to the PCO clinic of Taleghani Hospital who meet the inclusion criteria will enter the study after obtaining written consent. Patients are then randomly assigned to the synbiotic supplement group and the placebo group for 12 weeks. At the beginning and end of the intervention, 5 cc of blood is taken from the participating patients after 10 to 12 hours of fasting and the patients' anthropometric indices are measured. Before the intervention, sachets containing synbiotic or placebo supplements are coded by the factory as A and B so that the blinding of the researcher, statistical analyst and patients about the type of supplements received by each group is observed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People with PCOS according to Rotterdam criteria, age between 18 to 45 years and at least 2 weeks after diagnosis and treatment. Exclusion criteria: Inflammatory, liver, kidney disease and use of antibiotics in the past three months.

Intervention groups
Patients will be randomly divided into synbiotic (n=25) and control (n=25) groups and will receive a synbiotic sachet containing Bacillus coagulans or a similar sachet containing placebo for 12 weeks, respectively.

Main outcome variables
Fasting blood sugar, Serum insulin, Hemostatic model of insulin resistance and pancreatic β cell function (HOMA-IR and HOMA-β, respectively), Quantitative insulin sensitivity check index and Serum total testosterone

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150815023617N6**
Registration date: **2022-06-22, 1401/04/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-22, 1401/04/01**
Update count: **0**

Registration date
2022-06-22, 1401/04/01

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 22077424

Email address
golbonsohrab@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-22, 1401/04/01

Expected recruitment end date
2023-03-18, 1401/12/27
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of synbiotic supplement containing Bacillus coagulans on glycemic control, lipid profile, testosterone, systemic inflammation and anthropometric measurements in women with polycystic ovarian syndrome.

Public title
The effects of synbiotic supplement containing Bacillus coagulans on women with polycystic ovarian syndrome.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having polycystic ovary syndrome according to Rotterdam criteria At least 2 weeks after the diagnosis and treatment of PCOS Being in the age range of 18-45 years Being in the BMI range: 18.5-35 Willingness to cooperate
Exclusion criteria:
Being pregnant Having liver disease, Kidney failure and heart failure, Infectious or inflammatory diseases, Thyroid disorders, Diabetes, Cancers, Hyperprolactinemia Take supplements or products containing synbiotics or probiotics in the past month Taking antibiotics in the last three months Consumption of corticosteroids or omega-3
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization of women, the Stratified Blocked Randomization method based on BMI, use of hormonal drugs that modulate the menstrual cycle and metformin will be used.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In order to perform this research in a three blinded method, at the beginning of the study, the sachets containing synbiotic or placebo supplements are coded by the factory as A and B so that the lack of information of the researcher, statistical analyst and patients of the type of supplements received by each group is observed.
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Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of National Nutrition & Food Technology Research Institute
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town.
City
Tehran
Province
Tehran
Postal code
1998743664
Approval date
2022-02-21, 1400/12/02
Ethics committee reference number
IR.SBMU.NNFTRI.REC.1401.017

Health conditions studied

1

Description of health condition studied
Polycystic Ovarian Syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Fasting blood glucose (FBG)
Timepoint
Measurement of fasting blood sugar at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.
Method of measurement
Enzymatic method

2

Description
Serum Insulin
Timepoint
Measurement of serum insulin at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.
Method of measurement
Elisa method

3

Description
Serum total testosterone
Timepoint
Measurement of serum total testosterone at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.
Method of measurement
Elisa method

4

Description
HOMA-β: The homeostasis model assessment of pancreatic β-cell function
Timepoint
Measurement of HOMA-β at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.
Method of measurement
Calculating by formula: HOMA-β=360×Insulin (International Unit/mililiter)/Fasting glucose (miligram/deciliter) − 63

5

Description
HOMA-IR: Homeostatic model assessment of insulin resistance
Timepoint
Measurement of HOMA-IR at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.
Method of measurement
Calculating by formula: HOMA-IR = [FBG (miligram/deciliter)×Fasting Insulin (International Unit/mililiter)]/405.

6

Description
QUICKI: The quantitative insulin-sensitivity check index
Timepoint
Measurement of QUICKI at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.
Method of measurement
Calculating by formula: QUICKI = 1/[log fasting insulin (International Unit/mililiter)+log fasting glucose(miligram/deciliter)]

Secondary outcomes

1

Description
Serum triglyceride (TG)
Timepoint
Measurement of serum triglyceride at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.
Method of measurement
Enzymatic method

2

Description
Serum total cholesterol
Timepoint
Measurement of serum total cholesterol at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.
Method of measurement
Enzymatic method

3

Description
Low density lipoprotein cholestrol (LDL-C)
Timepoint
Measurement of low density lipoprotein cholestrol (LDL-C) at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.
Method of measurement
Enzymatic method

4

Description
High density lipoprotein cholestrol (HDL-C)
Timepoint
Measurement of high density lipoprotein cholestrol (HDL-C) at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.
Method of measurement
Enzymatic method.

5

Description
C reactive protein quantitive (CRP Quantitive)
Timepoint
Measurement of C reactive protein quantitive (CRP Quantitive) at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.
Method of measurement
Elisa method

6

Description
Weight
Timepoint

Measurement of weight at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.

Method of measurement

Body weight scale

7

Description

waist circumference

Timepoint

Measurement of waist circumference at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.

Method of measurement

Tape meter

8

Description

Hip circumference

Timepoint

Measurement of hip circumference at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.

Method of measurement

Tape meter

9

Description

Body mass index

Timepoint

Measurement of BMI at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.

Method of measurement

Calculating by formula: Weight in kilogram / the square of the height in centimeters

Intervention groups

1

Description

Intervention group: For 12 weeks, they will consume 1 sachet of synbiotic from Parsi Lact Co, Iran daily. Each 2 gram sachet contains 10 to the power of 10 CFU/g of Bacillus coagulans, 10 to the power of 10 CFU/g of Lactobacillus rhamnos, 10 to the power of 10 CFU/g of Lactobacillus helveticus, 500 mg of fructooligosaccharide and a 0.7% orange flavor.

Category

Treatment - Drugs

2

Description

Control group: For 12 weeks, they will consume 1 sachet of placebo from Parsi Lact Co, Iran daily. Each 2 gram sachet contains starch and a 0.7% orange flavor.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Women and PCOS Clinic of Ayatollah Taleghani Hospital

Full name of responsible person

Golbon Sohrab

Street address

Ayatollah Taleghani Hospital, Shahid A'arabi St., Shahid Chamran Highway, Yemen St., Tehran.

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Phone

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Fax

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Email

taleghanihospital@sbmu.ac.ir

Web page address

https://taleghani.sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Morteza Abdolahi

Street address

No. 7, Shahid Hafezi St. (West Arghavan), Shahid Farahzadi Blvd, Qods Town.

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Email

golbonsohrab@sbmu.ac.ir

Web page address

https://nutrition.sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Golbon Sohrab

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data is shared, such as the original outcome.

When the data will become available and for how long

The start of the access period is 12 months after printing the results.

To whom data/document is available

It will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The documentation can only be used for more complete studies in this field.

From where data/document is obtainable

Dr Golbon Sohrab Faculty member (assistant professor) at Faculty of Nutrition Sciences & Food Technology, Shaheed Beheshti University of Medical Sciences Email: golbonsohrab@sbmu.ac.ir

What processes are involved for a request to access

data/document

The communication will be possible through the electronic mail given in the previous section.

Comments