

# 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  $\beta$  cell function (HOMA-IR and HOMA- $\beta$ , 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@sbm.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.

**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**

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**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- $\beta$ : The homeostasis model assessment of pancreatic  $\beta$ -cell function

### **Timepoint**

Measurement of HOMA- $\beta$  at the beginning of the study (before the intervention) and 90 days after the start of synbiotic consumption.

### **Method of measurement**

Calculating by formula:  $HOMA-\beta = 360 \times \text{Insulin (International Unit/mililiter)} / \text{Fasting glucose (miligram/deciliter)} - 63$

## 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:  $HOMA-IR = [\text{FBG (miligram/deciliter)} \times \text{Fasting Insulin (International Unit/mililiter)}] / 405$ .

## 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:  $QUICKI = 1 / [\log \text{fasting insulin (International Unit/mililiter)} + \log \text{fasting glucose (miligram/deciliter)}]$

## **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 cholesterol (LDL-C)

### **Timepoint**

Measurement of low density lipoprotein cholesterol (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 cholesterol (HDL-C)

### **Timepoint**

Measurement of high density lipoprotein cholesterol (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 quantitative (CRP Quantitative)

### **Timepoint**

Measurement of C reactive protein quantitative (CRP Quantitative) 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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**Email**

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**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 Abdollahi

**Street address**

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

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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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No. 7, West Hafezi Ave., Farahzadi Blvd., Qods Town  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Golbon Sohrab  
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Assistant professor  
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**Other areas of specialty/work**  
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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**