Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The effects of synbiotic supplement containing Bacillus coagulans and fructooligosaccharide on Quality of life (physical and mental health status) in women with polycystic ovarian syndrome.

Protocol summary

Study aim

Determining the effects of synbiotic supplement containing Bacillus coagulans and fructooligosaccharide on the life quality (physical and mental health status) of women with polycystic ovary syndrome.

Design

A controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 60 patients. Block randomization method is used for randomization.

Settings and conduct

60 women over 18 years old with PCOS will be invited to participate. Then patients are asked to fill PCOSQ-26, SF-12 and PSS-10 questionnaires. Then the patients are randomly assigned to two groups, treatment or control. At the begining, the set of sachets containing synbiotic supplements or placebo are coded by the factory as A and B so that the researcher, statistical analyst and patients will stay uninformed.

Participants/Inclusion and exclusion criteria

inclusion criteria: Having polycystic ovary syndrome according to Rotterdam criteria, At least 2 weeks have passed since the diagnosis and treatment of PCOS, age range of over 18 years, BMI range of 18-5-35 Exclution criteria: pregnancy, suffering from liver diseases, suffering from kidney failure and heart failure, infectious or inflammatory diseases, suffering from thyroid disorders, diabetes, cancer, hyperprolactinemin, synbiotics or probiotics products in the last month, Use of antibiotics in the last three months, Adherence to special diets or weight loss diets during the last three months and Use of corticosteroids, omega-3

Intervention groups

The intervention will be carried out for 12 months on two treatment and control groups, who will receive 2 grams of synbiotic sachets containing Bacillus coagulans and fructooligosaccharide or 2 grams of placebo sachets, respectively.

Main outcome variables

Emotional, Hirsotism, weight, Infertility and menstrual scores of PCOSQ-26 Physical and mental performance scores (SF12) PSS-10 score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211108053007N1**
Registration date: **2023-02-14, 1401/11/25**
Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**
Update count: **0**

Registration date

2023-02-14, 1401/11/25

Registrant information

Name

Zahra Hariri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 7483

Email address

hariri.nut@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-19, 1401/11/30

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of synbiotic supplement containing Bacillus coagulans and fructooligosaccharide on Quality of life (physical and mental health status) in women with polycystic ovarian syndrome.

Public title

The effects of synbiotic supplement containing Bacillus coagulans and fructooligosaccharide on Quality of life (physical and mental health status) in women with polycystic ovarian syndrome.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed with polycystic ovary syndrome (PCOS) according to Rotterdam criteria At least 2 weeks have passed since the diagnosis and treatment of PCOS Being in the age range of 18-45 years Being in the BMI range of 18.5-35 Willingness to cooperate

Exclusion criteria:

pregnancy Having liver diseases, kidney failure and heart failure, infectious or inflammatory diseases, thyroid gland disorders, diabetes, types of cancer and hyperprolactinemia. Consuming supplements or products containing synbiotics or probiotics in the last month Adherence to special diets or weight loss diets during the last three months Taking corticosteroids or omega-3

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomly assign women, stratified block randomization method is used based on BMI, the use of hormonal drugs that regulate the menstrual cycle, and metformin.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo sachets are completely similar in appearance to synbiotic sachets. In order to carry out this research in a three-blind manner, at the time of the start of the study, the set of sachets containing synbiotic or placebo supplements are coded as A and B by the factory so that the researcher, statistical analyst and patients are not informed about the type of supplements received by each group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of vice-chancellor in Research Affairs - Shahd Beheshti University of Med

Street address

Ground floor, Building No. 2, Aarabi St,. Daneshjoo Blvd., Yaman St., Chamran Hwy.

City

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Province

Tehran

Postal code

1998743664

Approval date

2023-02-12, 1401/11/23

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.703

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

Emotional domain score of PCOSQ-26

Timepoint

At the beginning and 12 weeks after the start of the intervention

Method of measurement

PCOSQ-26 form

2

Description

Hirsotism domain score of PCOSQ-26

Timepoint
At the beginning and 12 weeks after the start of the intervention
Method of measurement
PCOSQ-26 form

3

Description
Weight domain score of PCOSQ-26
Timepoint
At the beginning and 12 weeks after the start of the intervention
Method of measurement
PCOSQ-26 form

4

Description
Infertility Problems domain score of PCOSQ-26
Timepoint
At the beginning and 12 weeks after the start of the intervention
Method of measurement
PCOSQ-26 form

5

Description
Menstrual Problems domain score of PCOSQ-26
Timepoint
At the beginning and 12 weeks after the start of the intervention
Method of measurement
PCOSQ-26 form

6

Description
Physical functioning score
Timepoint
At the beginning and 12 weeks after the start of the intervention
Method of measurement
SF-12 form

7

Description
Physical functioning score
Timepoint
At the beginning and 12 weeks after the start of the intervention
Method of measurement
SF-12 form

8

Description
Perceived Stress scale (PSS-10) score
Timepoint
At the beginning and 12 weeks after the start of the intervention
Method of measurement
PSS-10 form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For 12 weeks, they will receive daily one 2 gram sachet of synbiotic containing 10 to the power of 11 CFU/g of Bacillus coagulans, 10 to the power of 10 CFU/g Lactobacillus rhamnus, 10 to the power of 10 CFU/g Lactobacillus heloticus, 500 mg fructo-oligosaccharide and 0.7% orange flavor.
Category
Treatment - Drugs

2

Description
Control group: They will receive a placebo sachet daily containing 2 grams of starch and 0.7% orange flavoring.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Women's and pcos clinic of Ayatollah Taleghani Hospital
Full name of responsible person
Zahra Hariri
Street address
Shahid Aarabi St., Yaman St., Chamran Hwy.
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Phone
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Email
taleghani@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

Maryam Rezvani Fard

Street address
Ground floor, buliding No. 2, Shahid Aarabi St., Yemen St., Chamran Hwy.

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1998743664

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info@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
Zahra Hariri

Position
MCS Student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Person responsible for updating data

Contact

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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, such as the main results, will be shared.

When the data will become available and for how long

The beginning of the access period is 12 months after the publication of the results

To whom data/document is available

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

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

Zahra Hariri

What processes are involved for a request to access data/document

Communication will be possible through the email given in the previous section

Comments