

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Effect of Prebiotic in Clinical and Paraclinical Parameters of Poly Cystic Ovarian Syndrome (PCOS): A Triple Blind Randomized Clinical Controlled Trial

Protocol summary

Summary

Objectives: To determine the effect of prebiotics on the clinical and Para-clinical parameters of polycystic-ovarian syndrome
Design: Two-armed randomized controlled trial.
Conduct: This study will be conducted on 62 women referring to gynecology clinic of Alzahra and Taleghani Hospitals, and gland clinic of Imam Reza and Sina hospitals in Tabriz. Eligible individuals will be assessed according to the rotterdam criteria and if they have criteria, they will be referred to the research collaborator for final approval. After final diagnosis and person's willingness to participate in the study, primary evaluations will be conducted. Participants will be randomly assigned to two groups of intervention (receiving prebiotic or resistant dextrin) and control (receiving placebo or maltodextrin) using block randomization with block sizes of 4 and 6 the allocation ratio of 1:1. **Participants:** women ages 18-45 years old affected by polycystic ovarian syndrome. **Intervention:** The intervention group will receive one packet of 20 gram perbiotic and control group will receive one packet of 20 gram placebo that will use in the glass of water daily for three months. The main outcome variables include hirsutism mean score and hormonal indices (free testosterone and dihydroepiandrosterone sulphate) that will be assessed before, three and six months after starting the intervention. The secondary outcome variables include Anthropometric indices (Waist circumference, hip circumference and body mass index), serum levels of fasting blood sugar, hsCRP and lipid profile that will be assessed before, three and six months after starting the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062810324N33**

Registration date: **2016-07-28, 1395/05/07**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-07-28, 1395/05/07

Registrant information

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Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-08-01, 1395/05/11

Expected recruitment end date

2016-12-30, 1395/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Probiotic in Clinical and Paraclinical Parameters of Poly Cystic Ovarian Syndrom (PCOS): A Triple Blind Randomized Clinical Controlled Trial

Public title

Effect of Probiotic in Clinical and Paraclinical Parameters of Poly Cystic Ovarian Syndrom (PCOS)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Confirming the diagnosis of PCOS by research collaborator; Age between 18 and 45 years old; Having literacy of reading and writing for completing the questionnaires; BMI between 25 and 40 kg/m²; Not taking of probiotic, prebiotics, vitamins, minerals and omega-3 during the study and three months before the intervention Exclusion criteria: Having other androgenic disorders such as adrenal hyperplasia or Androgen-secreting tumor according to assessment of research collaborator; Having thyroid diseases according to assessment of research collaborator; Having Cushing's syndrome according to assessment of research collaborator; Using of hormonal contraceptive drugs at present or previous use of hormone therapy; Pregnancy or breast-feeding; Having previous surgery on one or both ovaries; Using of cigarettes and alcohol; Severe physical activity (this is activity that during carrying out it, an individual can't easily talk due to increased respiratory rate and breathing); Using of Dietary supplements

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan

City

Tabriz

Postal code

Approval date

2016-07-12, 1395/04/22

Ethics committee reference number

IR.TBZMED.REC.1395.286

Health conditions studied

1

Description of health condition studied

clinical parameters

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Hirsutism Score

Timepoint

Before study, three and six months after starting the intervention

Method of measurement

Ferriman-Gallwey criteria

2

Description

Serum Levels of hormonal indices (DHEA-S, free testosterone)

Timepoint

Before study and three months after starting the intervention

Method of measurement

Blood tests

Secondary outcomes

1

Description

Anthropometric indices (Waist circumference, hip circumference and body mass index)

Timepoint

before intervention, three and six months after starting the intervention

Method of measurement

Measuring with centimeter and scale

2

Description

Serum levels of FBS, hsCRP and Lipid profile

Timepoint

before intervention and three months after starting the intervention

Method of measurement

Blood tests

3

Description

Side events

Timepoint

During the study

Method of measurement

Checklist

Intervention groups

1

Description

The intervention group will receive one pocket of 20 gram perbiotic that will use in the glass of water daily for three months.

Category

Treatment - Other

2

Description

The control group will receive one pocket of 20 gram placebo that will use in the glass of water daily for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Sevda Gholizadeh shamasbi

Street address

Alzahra hospital, Tabriz

City

Tabriz

2

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Sevda Gholizadeh shamasbi

Street address

Emam Reza hospital, Tabriz

City

Tabriz

3

Recruitment center

Name of recruitment center

Talegani hospital

Full name of responsible person

Sevda Gholizadeh shamasbi

Street address

Talegani hospital, Tabriz

City

Tabriz

4

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Sevda Gholizadeh shamasbi

Street address

Sina hospital, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Mohammadreza Rashidi

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Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan

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Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Nursing & Midwifery, Tabriz University of
Medical Sciences

Full name of responsible person

Sevda Gholizadeh shamasbi

Position

Msc Student of Midwifery

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Fax**Email**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty