Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Prebiotic in Clinical and Paraclinical Parameters of Poly Cystic Ovarian Syndrom (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 pocket of 20 gram perbiotic and control group will receive one pocket 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

Name

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

Public title
Effect of Prebiotic 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 Univercity 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 testostrone)
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
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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
Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan
City
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
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Position
Msc Student of Midwifery

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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