Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Study the effects of probiotic supplementation on metabolic parameters and level of androgens in women with polycystic ovary syndrome: a randomized double-blind, clinical trial

Protocol summary

Study aim
Study the effects of probiotic supplementation on metabolic parameters and level of androgens in women with polycystic ovary syndrome: a randomized double-blind, clinical trial

Design
a randomized double-blind, clinical trial

Settings and conduct
This study was a double blind randomized clinical trial Which will be performed on 84 patients with polycystic ovary syndrome in the age range of 18-45 years. Patients will be randomly divided into two groups. The first group will receive probiotics (Saccharomyces boulardii) and the second group of placebo. The duration of the study will be 3 months In each case, a fasting blood sample will be taken from all patients before and after intervention. The levels of FBS, DHEAS sulfate and testosterone will be measured. Stata software will be used to analyze the data.

Participants/Inclusion and exclusion criteria
Inclusion criteria:patients whom have polycystic ovary syndrome based on the ultrasond tests; Exclusion criteria:hypertension, hyperprolactinemia, Renal failure, liver failure, heart failure, cushings syndrome, hyperthyroidism, hypothyroidism, cancer, smoking, diabetes, autoimmune disease

Intervention groups
the case group will receive 1 probiotic capsule daily for 3 months The control group will receive 1 plasebo capsule daily for 3 months

Main outcome variables
fasting blood sugar,testestrone,Dehydroepiandrosterone sulfate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180404039187N3**
Registration date: **2019-04-09, 1398/01/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-09, 1398/01/20**
Update count: **0**

Registration date
2019-04-09, 1398/01/20

Registrant information

Name
Elnaz Shaseb

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 1337 2250

Email address
shasebe@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-23, 1397/06/01

Expected recruitment end date
2019-05-22, 1398/03/01

Actual recruitment start date
2018-10-08, 1397/07/16

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study the effects of probiotic supplementation on

metabolic parameters and level of androgens in women with polycystic ovary syndrome: a randomized double-blind, clinical trial

Public title
Study the effects of probiotic supplementation on polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients whom have polycystic ovary syndrome based on the ultrasond tests
Exclusion criteria:
hypertension Hyperprolactinemia Renal failure Liver failure Heart failure Cancer Diabetes Hyperthyroidism Hypothyroidism Smoking
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: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Arrangement of the randomization process: 1) Determining the volume of each block (quadruple blocks) 2) Preparing the list of the blocks and assigning a number to each of them AABB(1) ABAB(2) ABBA(3) BBAA(4) BABA(5) BAAB(6) 3) Choosing random numbers between 1 and 6 4) Defining the treatment assignment list For example: AABB(1)_BBAA(4)_ABAB(2)_BABA(5)
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants (patients) and the researcher who has the task of sampling in the study, and the analyser are all blind during the study. At the patient's level, blindness will be done using a placebo, in which it will be given the probiotic to a group and placebo to another group, and patients will not be informed that they received a probiotic capsule or a placebo capsule that looks completely identical. The researcher will give patients a medicine or placebo only on the basis of lableA or B without knowing the nature of A, B, and according to the randomized list.
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 & Technology Dept, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golghast St, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2018-10-08, 1397/07/16
Ethics committee reference number
IR.TBZMED.REC.1397.599

Health conditions studied

1

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

Primary outcomes

1

Description
Fasting blood sugar level
Timepoint
At the beginning and 3 months later
Method of measurement
laboratory tests(enzymatic)

2

Description
testestrone
Timepoint
At the beginning and 3 months later
Method of measurement
laboratory tests(immuno assay)

3

Description
Dehydroepiandrosterone sulfate

Timepoint
At the beginning and 3 months later
Method of measurement
laboratory tests(immuno assay)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:daily administration of 1 probiotic capsule "DAILYEAST" for 3 months(a product of zist takhmir company)
Category
Treatment - Drugs

2

Description
Control group:daily administration of 1 plasebo capsule "DAILYEAST" for 3 months(a product of zist takhmir company)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Elnaz Ṡhaseb
Street address
Alzahra hospital, Southern Artesh Ave., Baghshomal Crossroad
City
Tabriz
Province
East Azarbaijan
Postal code
5138663134
Phone
+98 41 3553 9161
Email
alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abolghasem Jouyban
Street address
No. 2, Central Building, Tabriz University of Medical Sciences, Golgasht Ave,. Azadi Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3337 2250
Fax
+98 41 3335 9680
Email
Jouyban@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Elnaz Shaseb
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of pharmacy, Tabriz University of Medical Scince, Golgasht Ave,. Azadi Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 144933344198
Email
elnaz_shaseb_64@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Elnaz Shaseb

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy, Tabriz university of Medical Science, Golgaste Ave., Azadi Ave.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Phone
+98 144933344198

Email
Elnaz_shaseb_64@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Nazila Soroush

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy, Tabriz university of Medical Science, Golgast Ave., Azadi Ave.

City
Tabriz

Province
East Azarbaijan

Postal code
5166414766

Phone
+98 41 3386 0978

Email
soroushnazila@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available