

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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 ultrasound 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 label A 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 syndrome

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

testosterone

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 \$haseb

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 Science, 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