

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Assessment of the Effects of Spirulina Supplementation on Metabolic Factors in Polycystic Ovary Syndrome Patients

Protocol summary

Study aim

The aim of this study is to determine the effects of Spirulina supplementation on metabolic factors in patients with Polycystic Ovary Syndrome.

Design

Study design: parallel double-blind (both patients and researchers) clinical trial. Sample size 86, phase 3.

Randomization will be done using the lottery method.

Settings and conduct

Patients with Polycystic Ovary Syndrome referred to Farhikhtegan hospital affiliated to Islamic Azad University.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with Polycystic Ovary Syndrome based on the Rotterdam criteria in the age range of 18 to 45 years. Not following a special diet. Not addicted to alcohol or drug abuse. The patient should not be pregnant or breastfeeding. Criteria for not entering the study: history of oophorectomy, use of antidepressants, use of weight loss or appetite suppressants.

Intervention groups

Study intervention: Patients will be assigned to two groups of intervention (n=43) or control (n=43) to receive spirulina supplement or placebo. Spirulina and placebo supplement capsules are similar in shape and size. Fasting blood samples will be taken from the patients at the beginning of the study and 12 weeks after the intervention. Intervention time: 3 months.

Main outcome variables

Outcomes: Insulin metabolism markers (primary outcomes) and Blood Glucose and HemoglobinA1C and lipid profiles (secondary outcomes) will be measured at the beginning and end of the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220909055921N1**

Registration date: **2023-10-23, 1402/08/01**

Registration timing: **prospective**

Last update: **2023-10-23, 1402/08/01**

Update count: **0**

Registration date

2023-10-23, 1402/08/01

Registrant information

Name

Rezvan Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 5601

Email address

rezvan.mohammadi@srbiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-28, 1402/08/06

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the Effects of Spirulina Supplementation on Metabolic Factors in Polycystic Ovary Syndrome Patients

Public title

Effect of Supplementation in Polycystic Ovary Syndrome Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with polycystic ovary syndrome according to the Rotterdam criteria Age range from 18 to 45 years Not following a special diet Not addicted to alcohol or drug abuse The patient should not be pregnant or breastfeeding

Exclusion criteria:

History of oophorectomy Use of antidepressants Use of weight loss or appetite suppressants

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

It will be done in a simple random way using a lottery. In this way, a number or code is assigned to each patient and it is placed in a container and stirred. Out of 86 people, the first 43 people are in group A and the rest take in group B.

Blinding (investigator's opinion)

Double blinded

Blinding description

Spirulina supplement and Placebo were divided into two groups A and B by the manufacturer. Participants and researchers or outcome assessors know which group each patient received but are unaware of study group allocation.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Farhikhtegan Hospital

Street address

Daneshgah Ave.,Hesarak

City

Tehran

Province

Tehran

Postal code

1477899679

Approval date

2023-07-08, 1402/04/17

Ethics committee reference number

IR.IAU.FARHIKHTEGANH.REC.1402.002

Health conditions studied**1****Description of health condition studied**

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Serum High-Density Lipoprotein

Timepoint

The first day of the study and the last day of the 12th week

Method of measurement

Enzymatic method using Autoanalyzer

2**Description**

Total Serum Cholesterol

Timepoint

The first day of the study and the last day of the 12th week

Method of measurement

Enzymatic method using Autoanalyzer

3**Description**

Fasting Blood Sugar

Timepoint

The first day of the study and the last day of the 12th week

Method of measurement

Elisa Kit

4**Description**

Total Serum Triglyceride

Timepoint

The first day of the study and the last day of the 12th

week

Method of measurement

Enzymatic method using Autoanalyzer

5

Description

Serum Low-density Lipoprotein

Timepoint

The first day of the study and the last day of the 12th week

Method of measurement

Enzymatic method using Autoanalyzer

6

Description

Serum Insulin

Timepoint

The first day of the study and the last day of the 12th week

Method of measurement

Microunits per Milliliter, Enzyme immunoassay test (ELISA)

7

Description

HemoglobinA1C

Timepoint

The first day of the study and the last day of the 12th week

Method of measurement

High Performance Liquid Chromatography with Ion Exchange

Secondary outcomes

1

Description

Insulin Resistance Index

Timepoint

The first day of the study and the last day of the 12th week

Method of measurement

Formula

2

Description

Blood Pressure

Timepoint

The first day of the study and the last day of the 12th week

Method of measurement

mmHg, Barometer

3

Description

Weight

Timepoint

The first day of the study and the last day of the 12th

week

Method of measurement

Kilogram-Scale

4

Description

Body Mass Index

Timepoint

The first day of the study and the last day of the 12th week

Method of measurement

Kilogram/Square meter, Calculation (Weight/Height Square)

5

Description

Waist

Timepoint

The first day of the study and the last day of the 12th week

Method of measurement

Meter

Intervention groups

1

Description

Intervention group: Spirulina, 500 mg capsules, four times a day (morning, noon, evening, night), for 84 days

Category

Treatment - Drugs

2

Description

Control group: placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farhikhtegan Hospital

Full name of responsible person

Rezvan Mohammadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Seyedbabak Mozafari

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Mozafari@srbiau.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Rezvan Mohammadi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Rezvan Mohammadi

Position

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Latest degree

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Other areas of specialty/work

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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