Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

Effect of spirulina (Arthrospira plantensis) supplementation on nutritional status, hormonal status, cardiometabolic indices and clinical symptoms in women with polycystic ovary syndrome

Protocol summary

Study aim

The effect of spirulina (Arthrospira plantensis) supplementation on nutritional status, hormonal status, cardiometabolic indices and clinical symptoms in women with polycystic ovary syndrome

Design

A clinical trial with a control group, parallel groups, double-blind, randomized using RASS software, on 46 patients

Settings and conduct

Participants meeting the criteria will be assigned to intervention or placebo groups with the same protocol. Anthropometric assessments, relevant questionnaires, and a 5-cc fasting blood sample will be obtained at baseline and study completion for biochemical analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria included willingness to participate in the study; women diagnosed with polycystic ovary syndrome (PCOS) by a physician based on the Rotterdam criteria; age between 20 to 45 years; BMI between 25 and 35. Exclusion criteria consisted of a history of liver, kidney, cardiovascular diseases , diabetes , Cushing’s syndrome, or hyperprolactinemia; pregnancy or lactation; allergy to algae or seafood products; use of weight loss medications, oral contraceptive pills for contraception, regular physical activity, adherence to a specific diet, or use of any dietary supplements (including nutritional or herbal supplements) within the past three months; and smoking, alcohol consumption, or hookah use.

Intervention groups

The intervention group will consume three capsules of Spirulina algae daily, with a dose of 500 mg, while the placebo group will receive three capsules of maltodextrin identical in appearance and packaging to the supplement. Both groups will take the capsules with their meals to enhance absorption, for a duration of 12 weeks.

Main outcome variables

The nutritional status, hormonal status , cardiometabolic indices , and clinical symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250506065624N3**
Registration date: **2025-08-12, 1404/05/21**
Registration timing: **prospective**

Last update: **2025-08-12, 1404/05/21**
Update count: **0**

Registration date

2025-08-12, 1404/05/21

Registrant information

Name

Vahideh Ebrahimzadeh Attari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2025-12-22, 1404/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of spirulina (Arthrospira plantensis) supplementation on nutritional status, hormonal status, cardiometabolic indices and clinical symptoms in women with polycystic ovary syndrome

Public title

Effect of spirulina algae supplementation on nutritional status, hormonal status, cardiometabolic indices and clinical symptoms in women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women diagnosed with polycystic ovary syndrome (PCOS) based on physician assessment and the Rotterdam criteria Age between 20 and 45 years Body mass index (BMI) ranging from 25 to 35 kg/m² Willingness to participate in the study

Exclusion criteria:

Presence of hepatic, renal, cardiovascular diseases, diabetes mellitus, Cushing's syndrome, or hyperprolactinemia History of allergy to algae or seafood products Use of weight loss medications Use of oral contraceptive pills (OCPs) for birth control Pregnancy or lactation Engagement in a regular exercise program Adherence to a specific diet within the past three months Use of any type of supplement (including nutritional or herbal) within the past three months History of severe allergic reaction to a supplement or placebo Use of tobacco, alcohol, or hookah

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to either the intervention or placebo group using simple randomization through the Random Allocation Software (RASS). This software will automatically generate a random allocation sequence in which each participant will have an equal probability (50%) of being assigned to one of the two groups. In this method, the allocation of each individual will be entirely independent of others, and the order of participant enrollment will not influence the randomization process. To ensure allocation concealment, the random codes generated by the software will be placed in sealed, opaque, and sequentially numbered envelopes, to be opened in the order of participant enrollment. These codes will only indicate group designation (Group A or Group B), and both the investigators and participants will remain blinded to the actual content of the intervention (supplement or placebo) until data collection is complete. This procedure is intended to minimize allocation bias and enhance the internal validity of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, in order to minimize bias and enhance the validity of the results, a double-blind design will be employed, whereby neither the participants nor the principal investigator will be aware of the group assignments (intervention or control). The blinding process will be implemented according to the following steps: First, eligible participants will be randomly assigned to either the intervention or control group. To maintain impartiality, the allocation will be performed by an independent individual who will not be involved in data collection or data analysis. The intervention supplement and the placebo will be identical in appearance, color, size, odor, and packaging, and will be prepared by a pharmaceutical company. Each participant will receive the assigned product based on numerical coding (e.g., A and B). These codes will remain confidential with the individual responsible for blinding until the completion of data analysis. All participants will receive standardized instructions on how to consume the supplement, without any knowledge of their group assignment. Furthermore, the researcher responsible for data collection and analysis will remain blinded to the group allocations throughout the study. After the data collection phase is complete, the codes will be unblinded and the data will be analyzed accordingly. The use of this approach is expected to minimize the risk of both conscious and unconscious bias on the part of the researcher and the participants, thereby improving the internal validity of the study.

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

Talash Girls' Dormitory, Entrance of Tabriz University of Medical Sciences, Before Pishghadam Bridge, from Vali-Asr Hospital Direction, Middle Ring Road, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5163996937

Approval date
2025-06-30, 1404/04/09

Ethics committee reference number
IR.TBZMED.REC.1404.303

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
Testosterone hormone

Timepoint
At baseline and after 12 weeks of Spirulina supplementation

Method of measurement
Blood samples for testosterone measurement will be collected after a 10 to 12-hour overnight fast. Following collection, the blood samples will be kept at room temperature for 30 minutes to allow clot formation. The samples will then be centrifuged at 3,000 rpm for 10 minutes. The separated serum will be aliquoted into specific microtubes and stored at –80°C until analysis. Serum hormone concentrations will be measured using high-sensitivity ELISA kits, and all samples will be analyzed in a single batch.

2

Description
Dehydroepiandrosterone sulfate hormone

Timepoint
At baseline and after 12 weeks of Spirulina supplementation

Method of measurement
Blood samples for Dehydroepiandrosterone sulfate measurement will be collected after a 10 to 12-hour overnight fast. Following collection, the blood samples will be kept at room temperature for 30 minutes to allow clot formation. The samples will then be centrifuged at 3,000 rpm for 10 minutes. The separated serum will be aliquoted into specific microtubes and stored at –80°C until analysis. Serum hormone concentrations will be measured using high-sensitivity ELISA kits, and all samples will be analyzed in a single batch.

3

Description
Estradiol (E2) hormone

Timepoint
At baseline and after 12 weeks of Spirulina supplementation

Method of measurement
Blood samples for estradiol measurement will be collected after a 10 to 12-hour overnight fast. Following collection, the blood samples will be kept at room temperature for 30 minutes to allow clot formation. The samples will then be centrifuged at 3,000 rpm for 10 minutes. The separated serum will be aliquoted into specific microtubes and stored at –80°C until analysis. Serum hormone concentrations will be measured using high-sensitivity ELISA kits, and all samples will be analyzed in a single batch.

4

Description
Progesterone hormone

Timepoint
At baseline and after 12 weeks of Spirulina supplementation

Method of measurement
Blood samples for progesterone measurement will be collected after a 10 to 12-hour overnight fast. Following collection, the blood samples will be kept at room temperature for 30 minutes to allow clot formation. The samples will then be centrifuged at 3,000 rpm for 10 minutes. The separated serum will be aliquoted into specific microtubes and stored at –80°C until analysis. Serum hormone concentrations will be measured using high-sensitivity ELISA kits, and all samples will be analyzed in a single batch.

Secondary outcomes

1

Description
Weight

Timepoint
At baseline and after 12 weeks of Spirulina supplementation

Method of measurement
Patients’ body weight will be measured using a Seca scale with an accuracy of 0.5 kg, while they are barefoot and wearing minimal clothing.

2

Description
Body mass index(BMI)

Timepoint
At baseline and after 12 weeks of Spirulina supplementation

Method of measurement
Body mass index (BMI) will be calculated using the formula weight (kg) divided by the square of height (m), i.e., weight (kg)/height (m)².

3

Description
Waist circumference
Timepoint
At baseline and after 12 weeks of Spirulina supplementation
Method of measurement
Waist circumference of the participants will be measured using a flexible measuring tape at the midpoint between the lower margin of the last palpable rib and the top of the iliac crest, following a normal expiration.

4

Description
Hip circumference (HC)
Timepoint
At baseline and after 12 weeks of Spirulina supplementation
Method of measurement
Hip circumference will be measured using a flexible measuring tape at the point of the greatest protrusion of the buttocks.

5

Description
Body composition
Timepoint
At baseline and after 12 weeks of Spirulina supplementation
Method of measurement
Body composition will be assessed using a Tanita body analyzer.

6

Description
Appetite
Timepoint
At baseline and after 12 weeks of Spirulina supplementation
Method of measurement
Appetite will be assessed using a five-point questionnaire based on a Likert scale (with a response range from 0 to 10), the validity and reliability of which have been previously established.

7

Description
Energy intake
Timepoint
At baseline and after 12 weeks of Spirulina supplementation
Method of measurement
To assess energy intake, a three-day food diary questionnaire will be completed by the participants. Upon completion of the questionnaire, the amount of each food item consumed will be calculated in grams, and the average three-day daily energy intake for each individual will be determined using the Nutritionist IV software.

8

Description
Macronutrients
Timepoint
At baseline and after 12 weeks of Spirulina supplementation
Method of measurement
To assess macronutrient intake, a three-day food diary questionnaire will be completed by the participants. Upon completion of the questionnaire, the amount of each food item consumed will be calculated in grams, and the average three-day macronutrients intake for each individual will be determined using the Nutritionist IV software.

9

Description
Micronutrients
Timepoint
At baseline and after 12 weeks of Spirulina supplementation
Method of measurement
To assess micronutrient intake, a three-day food diary questionnaire will be completed by the participants. Upon completion of the questionnaire, the amount of each food item consumed will be calculated in grams, and the average three-day micronutrients intake for each individual will be determined using the Nutritionist IV software.

10

Description
Fasting Blood Glucose
Timepoint
At baseline and after 12 weeks of Spirulina supplementation
Method of measurement
At the beginning and end of the study, after selecting eligible participants and grouping them, blood samples for measuring fasting blood glucose will be collected after a 10 to 12-hour overnight fast. After collection, the blood samples will be kept at room temperature for 30 minutes to allow clot formation, followed by centrifugation at 3,000 rpm for 10 minutes. The serum will be separated and aliquoted into specific microtubes and stored at –80°C until analysis and all samples will be analyzed in a single batch.

11

Description
Insulin
Timepoint

At baseline and after 12 weeks of Spirulina supplementation

Method of measurement

At the beginning and end of the study, after selecting eligible participants and grouping them, blood samples for measuring insulin indices will be collected after a 10 to 12-hour overnight fast. After collection, the blood samples will be kept at room temperature for 30 minutes to allow clot formation, followed by centrifugation at 3,000 rpm for 10 minutes. The serum will be separated and aliquoted into specific microtubes and stored at –80°C until analysis. Serum insulin concentration will be measured using high-sensitivity ELISA kits, and all samples will be analyzed in a single batch.

12

Description

Total Cholesterol

Timepoint

At baseline and after 12 weeks of Spirulina supplementation

Method of measurement

At the beginning and end of the study, after selecting eligible participants and grouping them, blood samples for measuring total cholesterol will be collected after a 10 to 12-hour overnight fast. After collection, the blood samples will be kept at room temperature for 30 minutes to allow clot formation, followed by centrifugation at 3,000 rpm for 10 minutes. The serum will be separated and aliquoted into specific microtubes and stored at –80°C until analysis and all samples will be analyzed in a single batch.

13

Description

Triglyceride

Timepoint

At baseline and after 12 weeks of Spirulina supplementation

Method of measurement

At the beginning and end of the study, after selecting eligible participants and grouping them, blood samples for measuring triglyceride will be collected after a 10 to 12-hour overnight fast. After collection, the blood samples will be kept at room temperature for 30 minutes to allow clot formation, followed by centrifugation at 3,000 rpm for 10 minutes. The serum will be separated and aliquoted into specific microtubes and stored at –80°C until analysis and all samples will be analyzed in a single batch.

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Description

High-Density Lipoprotein Cholesterol (HDL-C)

Timepoint

At baseline and after 12 weeks of Spirulina supplementation

Method of measurement

At the beginning and end of the study, after selecting eligible participants and grouping them, blood samples for measuring High-Density Lipoprotein Cholesterol will be collected after a 10 to 12-hour overnight fast. After collection, the blood samples will be kept at room temperature for 30 minutes to allow clot formation, followed by centrifugation at 3,000 rpm for 10 minutes. The serum will be separated and aliquoted into specific microtubes and stored at –80°C until analysis and all samples will be analyzed in a single batch.

15

Description

Low-Density Lipoprotein Cholesterol (LDL-C)

Timepoint

At baseline and after 12 weeks of Spirulina supplementation

Method of measurement

At the beginning and end of the study, after selecting eligible participants and grouping them, blood samples for measuring Low-Density Lipoprotein Cholesterol will be collected after a 10 to 12-hour overnight fast. After collection, the blood samples will be kept at room temperature for 30 minutes to allow clot formation, followed by centrifugation at 3,000 rpm for 10 minutes. The serum will be separated and aliquoted into specific microtubes and stored at –80°C until analysis and all samples will be analyzed in a single batch.

16

Description

Systolic Blood Pressure

Timepoint

At baseline and after 12 weeks of Spirulina supplementation

Method of measurement

The systolic blood pressure of the participants will be measured by the investigator using a mercury sphygmomanometer.

17

Description

Diastolic Blood Pressure

Timepoint

At baseline and after 12 weeks of Spirulina supplementation

Method of measurement

The diastolic blood pressure of the participants will be measured by the investigator using a mercury sphygmomanometer.

18

Description

Hirsutism

Timepoint

At baseline and after 12 weeks of Spirulina supplementation

Method of measurement

To assess hirsutism, the modified Ferriman-Gallwey (mFG) score will be used, in which hair growth in 9 different body areas (such as the face, chest, and

abdomen) will be evaluated on a scale from 0 to 4, and the total score will determine the severity of hirsutism. Additionally, for the overall evaluation of clinical symptoms related to PCOS, the modified PCOS Health-Related Quality of Life Questionnaire (MPCOSQ) will be used.

19

Description
Acne
Timepoint
At baseline and after 12 weeks of Spirulina supplementation
Method of measurement
To assess acne, the Global Acne Grading System (GAGS) will be used, which evaluates the severity of acne in different body areas based on the type of lesions (such as comedones, papules, pustules, and nodules) and assigns scores accordingly. Additionally, for the overall evaluation of clinical symptoms related to PCOS, the modified PCOS Health-Related Quality of Life Questionnaire (MPCOSQ) will be used.

20

Description
Menstrual cycle
Timepoint
At baseline and after 12 weeks of Spirulina supplementation
Method of measurement
To assess the menstrual cycle, the modified PCOS-related Health-Related Quality of Life questionnaire (MPCOSQ) will be used in the study

Intervention groups

1

Description
Intervention group: The spirulina supplementation, with a dose of 500 mg, will be taken three times daily with meals for better absorption over a period of 12 weeks, provided by (Goldspir Iran Company).
Category
Treatment - Other

2

Description
Control group: The maltodextrin supplement, with the same appearance and packaging as the spirulina supplement, will be taken three times daily with meals for better absorption over a period of 12 weeks, provided by (Goldspir Iran Company)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sheikh Al Rais Clinic
Full name of responsible person
-
Street address
Azadi St., before reaching Golgasht St
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Province
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-
Phone
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Email
nlfbrn79@gmail.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Khosrow Adib kia
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-
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Email
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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
Niloofar Barani

Position
-

Latest degree
Master

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
there are not extra data more than results presented in our articles

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

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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
No - There is not a plan to make this available

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