

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of spirulina supplementation on metabolic profile and clinical manifestation in women with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study is to determine the effects of spirulina supplementation on metabolic profile and clinical manifestation in women with polycystic ovary syndrome (PCOS).

Design

Clinical trial with control group, parallel groups, double-blind (both patients and researchers), randomized, 60 women with PCOS, phase 2

Settings and conduct

Population and sample size: 60 women with PCOS eligible and referred to Gynecology Clinic (Shahid Beheshti hospital) affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected in the study. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. Time of intervention: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with polycystic ovary syndrome according to Rotterdam criteria and aged 25 to 40 years will be included in this study. Exclusion criteria: Unwillingness to cooperate.

Intervention groups

Intervention group: 500 mg spirulina oral capsule, twice a day, for 12 weeks. Control group: Placebo oral capsule contain starch, twice a day, for 12 weeks.

Main outcome variables

Clinical symptoms and Fasting plasma glucose (primary outcome) and Total cholesterol, Triglycerides and HDL (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230122057180N1**

Registration date: **2023-01-24, 1401/11/04**

Registration timing: **prospective**

Last update: **2023-01-24, 1401/11/04**

Update count: **0**

Registration date

2023-01-24, 1401/11/04

Registrant information

Name

Elahe Heydarian fard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

Email address

heydarianfard-e@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-09, 1401/11/20

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of spirulina supplementation on metabolic profile and clinical manifestation in women with polycystic ovary syndrome

Public title

Effect of spirulina in treatment of polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with polycystic ovary syndrome according to Rotterdam criteria Women aged 25-40 years Complete informed consent

Exclusion criteria:

Hyperprolactinemia Thyroid disorders Subjects following a special diet or consuming drugs with an effect on hormonal profile like oral contraceptives (OCP) Steroid hormones, or any other drugs probably to affect ovarian action in the last 3 months Type 2 diabetes mellitus (T2DM) Cushing's syndrome Smokers Unwillingness to cooperate

Age

From **25 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed with simple method and random numbers generated by computer software (Stat Trek software) which choose the random numbers. Then, we consider the specific numbers for both groups for example: the even numbers are for intervention group and the odd numbers are for the placebo group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of supplements. Supplements and placebos are only the code is written on the packages. Patients and researcher do not know the type of intervention and after analyzing the data, packet codes are decoded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Faculty of Medicine & Dentistry- Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8814187159

Approval date

2022-09-04, 1401/06/13

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1401.106

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

Clinical symptoms

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire PCOS (Based on NIH criteria)

2

Description

Fasting plasma glucose

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

Secondary outcomes

1

Description

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

2

Description

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

3

Description

HDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Intervention group: 500 mg spirulina oral capsule (Khalije Fars Biotechnology Development Company, Tehran-Iran), twice a day, for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Placebo oral capsule contain starch (Khalije Fars Biotechnology Development Company, Tehran- Iran), twice a day, for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology Clinic (Shahid Beheshti hospital)

Full name of responsible person

Fatemeh Foroozanfard

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Ghotbe Ravandi Boulevard, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Elahe Heydarianfard

Position

Resident of obstetrics and gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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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

Dr. Elahe heydarianfard is committed to presenting all the achievements of the project in accordance with the framework of the National Institute for Medical Research Development in the Islamic Republic of Iran.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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