Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Astaxanthin supplementation on the insulin sensivity, lipid profile, and clinical symptoms in women with PCOS: A randomized clinical study

Protocol summary

Study aim

The primary objective of this trial is to investigate the effect of administration of 10 mg per day Astaxanthin (AST) for 12 weeks on clinical symptoms compared with control group in women with PCOS. Secondary aims are to determine the effect of 10 mg per day AST administration for 12 weeks on insulin sensitivity, lipid profile, circulating MDA level, and depression in women with PCOS.

Design

Double-blind randomized clinical trial with parallel group, on 44 patients with concealed randomisation by Permuted Block Randomization method.

Settings and conduct

Eligible women with PCOS who refer to the collaborating gynecologist clinic Isfahan, Iran, in 2023–2024, will be recruited in this study. After explaining the objectives of the study, written informed consent will be obtained from all participants. All participants will have a project-specific code that will be used during all analyses of the data. We will use the SPIRIT reporting guidelines to describe this protocol.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Eligible women with PCOS who refer to the collaborating gynecologist clinic Isfahan, Iran, in 2023–2024 Exclusion criteria: Pregnancy or breastfeeding, the presence of chronic inflammatory diseases, antioxidant supplementation intake in the last three months

Intervention groups

Subjects in intervention group will receive one capsule congaing 10 mg AST per day made by "Zyest Technology Tarawat Zendig" institue in Iran. Subjects in placebo group will intake one capsule containing corn starch in a wrapped and covered form and appearance of AST supplementation.

Main outcome variables

Clinical symptoms Insulin sensitivity Lipid profile Circulating Malondialdehyde levels Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231001059573N1**
Registration date: **2023-10-10, 1402/07/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-10, 1402/07/18**
Update count: **0**

Registration date

2023-10-10, 1402/07/18

Registrant information

Name

nafiseh Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1668 5490

Email address

nafiseh.shokri@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Astaxanthin supplementation on the insulin sensivity, lipid profile, and clinical symptoms in women with PCOS: A randomized clinical study

Public title

Efeect of Astaxanthin supplementation in women with Polycystic ovary syndrome (PCOs)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

PCOS diagnosis according to Rotterdam 2003 criteria Have a body mass index of 25-35 kg/m 2 Absence of pregnancy and breastfeeding No intake of medicine Not willing to get pregnant during the study

Exclusion criteria:

Ongoing pregnancy Changing their usual diet or eating habits or level of physical activity Presence of Skin or digestive allergy symptoms or any complications by intake of Astaxanthin supplementation Smoking or alcohol consumption

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into 2 groups to receive astaxanthin supplement or placebo using the Permuted Block Randomization method. In this method, for selection of block size, we choose the block size 4 for this study (step1). For formation of blocks, participants are grouped into sets of four (step 2). For randomization within blocks within each block, randomization is performed using random number table. The key is that the treatment assignments within each block are randomly allocated (step 3). For balanced allocation, after randomizing the participants within a block, the number of participants assigned to each treatment group should be equal or as close to equal as possible (step 4). For the last step, steps 3 and 4 are repeated for each block of participants until all participants have been assigned to a treatment group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the person who performs the blood test, the person who prescribes the supplements and participants do not know about the division of people into two drug and placebo groups. In this randomised trial, the person who analyzes the data (statistician) will generate allocation sequence, and assign participants to interventions randomly. Since the astaxanthin supplement and placebo are completely similar in terms of color and shape, patients are also not aware of this division. All baseline assessments will be undertaken prior to randomization and some assessments will be undertaken blinded for group allocation. All incoming data, including questionnaires and laboratory tests are collected by expert investigators in considered data sheets, and reviewed by the trial coordinator at the the Ethics Committee of Isfahan University of Medical Science to promote data quality. Both participants in AST and placebo groups are coded by the pharmaceutical company (code A and B). So, the investigators and participants will not be informed about allocation and the cods will be concealed until end of study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Science

Street address

Hezarjareeb street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2023-09-21, 1402/06/30

Ethics committee reference number

IR.MUI.RESEARCH.REC.1402.204

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
Effect of 10 mg/day Astaxanthin supplementation for 12 weeks on severity of hirsutism in women with PCOS
Timepoint
At the baseline, and the end of the study
Method of measurement
To assess severity of hirsutism, the amount of total body hair in nine sits (upper lip, chin, chest, upper and lower abdomen, thigh, upper and lower back, and upper arm) will be evaluated according the modified Ferriman–Gallwey (mFG) scoring system. In this system, each individual body sit will be visually scored on a scale of 0 to 4, and the maximum score of each participants could be 16. The final score of 0 to 3 will be measured non-hirsutism, 4 to 7 will be considered mild hirsutism, and 8 Up to 11 and 12 to 16 will be reflected moderate hirsutism and severe hirsutism, respectively. Subjects will be asked to not use any removing hair methods during the study.

2

Description
Effect of 10 mg/day Astaxanthin supplementation for 12 weeks on circulating Malondialdehyde levels in women with PCOS
Timepoint
At the baseline, and the end of the study
Method of measurement
Serum Malondialdehyde (MDA) values will be measured by the TBARS method (Arsam Far Biot Company kit) and with a spectrophotometer or fluorimeter.

Secondary outcomes

1

Description
Efffect of 10 mg/day Astaxanthin administration for 12 weeks on insulin sensitivity in women with PCOS
Timepoint
At the baseline, and the end of the study
Method of measurement
To measure the serum glucose level, it will be converted to glucuronic acid by the activity of glucose oxidase, and the glucose concentration will be calculated using the quinonimine indicator. Fasting insulin will be measured by enzyme immunoassay methods. HOMA-IR index will be used to evaluate insulin resistance. To calculate the HOMA-IR index, fasting insulin (U/mlμ) and fasting blood glucose (nmol) will be used: HOMA-IR = fasting insulin (μU/L) x fasting glucose (nmol/L)/22.5. Serum Malondialdehyde (MDA) values will be measured by the TBARS method (Arsam Far Biot Company kit) and with a spectrophotometer or fluorimeter.

2

Description
Effect of 10 mg/day AST administration for 12 weeks on lipid profile in women with PCOS
Timepoint
At the baseline, and the end of the study
Method of measurement
Serum values of lipid profile (triglyceride, total cholesterol, LDL-c, HDL-c, cholesterol) are measured by enzymatic colorimetric methods. Lipase enzyme is used to measure TG, which converts TG into glycerol and fatty acid.

Intervention groups

1

Description
Intervention group: Astaxanthin
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Gynecology Clinic of Shariati Hospital
Full name of responsible person
Dr. Mehrnosh Samadi
Street address
Hezarjareeb street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 913 125 4752
Fax
+98 31 3668 8597
Email
nafiseh.shokri.m@gmail.com
Web page address
https://med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Golamreza Askari
Street address
Hezarjareeb street
City
Isfahan

Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 7898
Email
research@mui.ac.ir
Web page address
https://research.mui.ac.ir/fa/mrde

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Isfahan university of medical science

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
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Nafiseh Shokri
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hezarjareeb street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
nafiseh.shokri@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Nafiseh Shokri
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hezarjareeb street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
nafiseh.shokri@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Laya Saeed
Position
MSc Student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Hezarjareeb street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
laya.saeed@yahoo.com

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 is no further information

Study Protocol
Yes - There is 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
No - There is not a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The individual data of the participants in the study can be used without identifying names.

When the data will become available and for how long

period of availability: from 1403

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Data analysis is unimpeded.

From where data/document is obtainable

Postal address for correspondence, or email address

What processes are involved for a request to access data/document

Maximum 2 months

Comments