Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Astaxanthin effect on serum inflammatory markers and expression of genes related to ER stress and apoptosis pathway in peripheral blood mononuclear cell in polycystic ovary syndrome women

Protocol summary

Study aim

Determining the relationship between astaxanthin consumption and plasma inflammatory factors Hs-CRP, IL-18, TNFα, -IL-6, IL-1b, NF-κB and, expression of genes related to endoplasmic reticulum pathway and apoptosis in Pbmc

Design

This Triple-blind randomized clinical trial, controlled by placebo, based on the guidelines contained in the Helsinki Declaration, after obtaining permission from the ethics committee of Tehran University of Medical Sciences, 501 patients will be recruited. Prior to the intervention, written informed consent will be obtained from all participants

Settings and conduct

The location of the experiment:Tehran University of Medical Sciences. Sampling location: Omid fertility center. Isolation of blood serum and measurement of inflammatory factors - Isolation of pripheral blood mononuclear cells (Pbmc)- Assessment of the expression of ER stress and apoptotic pathway genes in pbmc;

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with PCOS-induced infertility at the age of 18-40 years. Exclusion criteria: pregnancy; adrenal hyperplasia; androgen-secreting tumors; hyperprolactinemia; thyroid dysfunction; diabetes or glucose tolerance disorder and male infertility factors.

Intervention groups

Astaxanthin consumer. Placebo consumer.

Main outcome variables

Plasma inflammatory factors include Hs-CRP, IL-18, IL-6, TNF-α, IL-1β and NF-κB; Endoplasmic reticulum stress pathway and apoptosis genes in Pbmc: ATF4, ATF6, XBP1, GRP78, CHOP, DR5, BCL2, BAX.Caspase8

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201029049183N2**
Registration date: **2022-04-12, 1401/01/23**
Registration timing: **prospective**

Last update: **2022-04-12, 1401/01/23**
Update count: **0**

Registration date

2022-04-12, 1401/01/23

Registrant information

Name

Masoome Jabarpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6405 3329

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Astaxanthin effect on serum inflammatory markers and expression of genes related to ER stress and apoptosis pathway in peripheral blood mononuclear cell in polycystic ovary syndrome women

Public title
Effect of Astaxanthin in treatment of PCOS
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Oligo/anovulation (ovulationabnormality) Hyperandrogenism Polycystic ovaries on ultrasound
Exclusion criteria:
Pregnancy Adrenal hyperplasia Androgen-secretingtumors Hyperprolactinemia Thyroid dysfunction Diabetes mellitus or glucose tolerance Male infertility factors
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible patients will be randomly assigned to the study after visiting the gynecology clinic. Randomization will be in the form of blocking in such a way that the method of replacement blocks is used within each floor. The blocks will be binary, consisting of AB and BA. The randomization tool will be a table of random numbers, that using the sequence AB for numbers zero through 4 in the random number table and the sequence BA for 5 to 9.It should be noted that the letter A means the intervention group and the letter B means the control group For hiding we use concealment allocation in a way that before the individual is assigned, the assigned group is not specified. In this method, each of the random sequences created on a cards are placed in the closed envelopes. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the time of registration of participants, based on the order of entry of the eligible participants in the study, one of the closed envelopes will be opened and the assigned group of the participant will be revealed.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study will be a three-way blind and the patient, researcher and statistical analyst of the patients' group therapy have no information and the decoder is outside the research team. The drug under study (Astaxanthin) and placebo in a completely similar shape and appearance, each of which is 60 in the same bottle instead of the drug will be provided to the subjects based on random allocation. It should be noted that the drug content of each The bottles are code-tagged on the bottles by the by someone outside the research team consultant and the research team is not aware of their interpretation.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Building no.1, Northern gate of the university, Poursina St. Qods St. Enqelab St
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2021-12-11, 1400/09/20
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.1051

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
ER stress and apoptotic factor
Timepoint
Before and 60 days after the intervention
Method of measurement

real time pcr

2

Description
Plasma inflammatory factors
Timepoint
Before and 60 days after the intervention
Method of measurement
ELISA KIT

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Astaxanthin consumption. In this group, patients take 12 mg of astaxanthin daily (in 2 capsules of 6mg twice in the morning and at night) for 60 days. Their routine treatment, metformin, does not stop.
Category
Treatment - Drugs

2

Description
Control group: Placebo consumption. In this group, patients take 12 mg of placebo daily (in 2 capsules of 6mg twice in the morning and at night) for 60 days. Their routine treatment does not stop with metformin.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid fertility clinic
Full name of responsible person
Dr. Ashraf Alyasin
Street address
Tehran, Darvazeh Shemiran St., Baharestan St., Shahid Meshki St. (Fakhrabad), next to the Romanian Embassy, No. 87
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Web page address
http://www.omidfertilityclinic.com/default.aspx

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.Mohammad Ali Sahraian
Street address
Tehran University of Medical Sciences, Keshavarz blvd. Ghods st.
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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
Tehran 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
Tehran University of Medical Sciences
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dr.fardin amidi
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Masoomjabarpour@ut.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
All data obtained in the research will be published in one of the valid and related scientific journals.
When the data will become available and for how long
2023
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
The data of this study can be used as an adjuvant therapy in patients with polycystic ovary syndrome underwent IVF/ICSI.
From where data/document is obtainable
Masoome jabarpour
What processes are involved for a request to access data/document
By sending an email to the corresponding author.
Comments