

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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, TNF $\alpha$ , -IL-6, IL-1 $\beta$ , NF- $\kappa$ B 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 peripheral 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- $\alpha$ , IL-1 $\beta$  and NF- $\kappa$ B; 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

masoomjabarpour@ut.ac.ir

##### 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 (ovulation abnormality)  
Hyperandrogenism Polycystic ovaries on ultrasound

### Exclusion criteria:

Pregnancy Adrenal hyperplasia Androgen-secreting tumors 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 analyster

## 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

omidivf@yahoo.com

**Web page address**

<http://www.omidfertilityclinic.com/default.aspx>

**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

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Tehran, Darvazeh Shemiran St., Baharestan St., Shahid Meshki St. (Fakhrabad), next to the Romanian Embassy, No. 87

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr.Mohammad Ali Sahraian

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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

**Full name of responsible person**

dr.fardin amidi

**Position**

professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Anatomy

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Masoom Jabarpour  
**Position**  
PhD student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Anatomy

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## 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

Masoom jabarpour

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

By sending an email to the corresponding author.

### Comments