

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Assessing the effect of Astaxanthin Phytochemical, Vitamin D3, Omega-3 and Vitamin E supplement on the severity of COVID-19 Symptoms of Patients with mild to Moderate Severity- a randomized double blind controlled Clinical Trial

#### Protocol summary

##### Study aim

Determining the effects of Astaxanthin , Vitamin D3, Omega-3 and Vitamin E supplement on the severity of COVID-19 in patients with mild to moderate COVID-19

##### Design

Randomized double blind controlled trial phase 2 with a parallel group design of 40 patients, randomized using random digit table

##### Settings and conduct

This double blinded study will be performed in Fayaz Bakhsh Hospital. At base line and after 7 days of intervention with supplement/placebo, patients will be assessed by general physician for respiratory rate, heart rate, O2 saturation, fever, anosmia, and headache. At baseline and at the end of the study total lymphocyte and notrophil count, ESR, CRP& ferritin will be evaluated. Samples will be collected for assessing IL-6 and TNF- $\alpha$  at baseline and at the end of the study and will be stored in -70 degree till the time of assessment. Data will be analyzed using SPSS 21.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Positive test for COVID-19 according to World Health Organization criteria and diagnosed with COVID-19 of mild to moderate severity Willingness to participate in the project age>18 years Exclusion criteria: Diagnosed with severe COVID-19 Pregnancy Using Omega-3 and/or vitamin E in 2 months before study initiation Vitamin D deficiency Enteral or parenteral nutrition need Need for Intensive Care Unit admission

##### Intervention groups

Patients will receive Astaxanthin Phytochemical, Vitamin D3, Omega-3 and Vitamin E capsule or placebo BD for 7 days. Each capsule contains 20 mg Astaxanthin, 200 mg omeg-3, 30 mg vitamin E, and 1000 IU vitamin D in intervention group or maltodextrine in placebo group.

##### Main outcome variables

Effect of above mentioned supplement on O2 saturation, IL-6 and TNF- $\alpha$

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140804018677N9**

Registration date: **2021-06-19, 1400/03/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-06-19, 1400/03/29**

Update count: **0**

##### Registration date

2021-06-19, 1400/03/29

##### Registrant information

##### Name

soodeh razeghi Jahromi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6634 8500

##### Email address

razeghi@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-28, 1400/03/07

##### Expected recruitment end date

2021-07-29, 1400/05/07

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Assessing the effect of Astaxanthin Phytochemical, Vitamin D3, Omega-3 and Vitamin E supplement on the severity of COVID-19 Symptoms of Patients with mild to Moderate Severity- a randomized double blind controlled Clinical Trial

**Public title**

Effect of Astaxanthin Phytochemical, Vitamin D3, Omega-3 and Vitamin E supplement on severity of mild to moderate COVID-19 Symptoms

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Positive test for COVID-19 according to WHO criteria and diagnosed with COVID-19 of mild to moderate severity  
Willingness to participate in the project age>18 years

**Exclusion criteria:**

Diagnosed with severe COVID-19 according to WHO criteria  
Pregnancy Using Omega-3 and/or vitamin E in 2 months before study initiation  
Vitamin D deficiency  
PN or EN need  
Need for ICU admission

**Age**

From 18 years old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: 40

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants will have equal chance to be assigned to studied groups. We will use random digits table to make random sequence. After determining the first number, we will continue downward and allocate even numbers to cases and odd numbers to placebo. As in small sample sizes, it would be probable that one group be completed earlier, if one group completed earlier, we will allocate the other assigned numbers to other group. A person out of study group will put her figure on one digit of the table with closed eyes and according to assumed agreement will go downward through the table and write the numbers down until completing the sample size in each group. Code "A" will allocated to even numbers and considered as "intervention group" and code "B" will allocated to odd numbers and considered as "placebo group". At the end we will have the sequence of 40

specific numbers and A&B codes. A person out of study team will put the numbers in sealed packets till the time of sampling

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

It is a double blind study. A third person out of study team have the sequence of codes that provide the team with sealed pockets containing allocation code at the time of sampling. The following groups of people involved in the trial: participants, Research team including principle investigator, data collectors, and outcome assessors will be blind.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of National Nutrition and Food Technology Reseach Institute

**Street address**

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Approval date**

2020-09-27, 1399/07/06

**Ethics committee reference number**

IR.SBMU.NNFTRI.REC.1399.065

**Health conditions studied****1****Description of health condition studied**

Covid-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

**Primary outcomes****1****Description**

respiratory rate

**Timepoint**

baseline and at the end of the study

**Method of measurement**

pulsoximeter

**2****Description**

pulse rate

**Timepoint**

baseline and at the end of the study

**Method of measurement**

Wrist radial atrial pulse

**3****Description**

Interlukin-6

**Timepoint**

baseline and at the end of the study

**Method of measurement**

ELISA

**4****Description**

Tumor necrotising factor alpha

**Timepoint**

baseline and at the end of the study

**Method of measurement**

ELISA

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: 20 mg Astaxanthin, 200 mg omeg-3, 30 mg vitamin E, and 1000 IU vitamin D per cap for 7 days, BD

**Category**

Treatment - Drugs

**2****Description**

Control group: placebo containing maltodextrine-for 7 days

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Fayaz Bakhsh Hospital

**Full name of responsible person**

Soodeh Razeghi Jahromi

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soodehrazeghi@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

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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**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Soodeh Razeghi Jahromi

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Person responsible for scientific inquiries**

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**Name of organization / entity**

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**Full name of responsible person**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data would be available to public

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

To all

**Under which criteria data/document could be used**

No other criteria

**From where data/document is obtainable**

Email to soodehrazeghi@gmail.com

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

sending email

**Comments**