Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Assessing the effect of Astaxanthin Phytochemical, Vitamin D3, Omega-3 and Vitamin E سupplement 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-α 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-α

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)

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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 سupplement 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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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
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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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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,
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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 updating data

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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 critaria
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