

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

The effect of Omega-3 supplementation on Inflammatory biomarkers and total Blood cell counts of Patients with Covid-19

Protocol summary

Study aim

Determining the effect of omega-3 supplementation on inflammatory activity and blood cell status in patients with COVID-19

Design

This study will be a randomized double-blind randomized controlled clinical trial with 40 patients with COVID-19. The subjects will be assigned to the intervention group and the placebo group by block randomization method.

Settings and conduct

This study will be performed in shariati hospital in Tehran. The intervention group received omega-3 supplements for two weeks and the control group received the same number of placebo. The evaluation of variables is done at the beginning and end of the study by sampling the patient's blood.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Being 20 to 65 years old 2. Detection of COVID-19 based on PCR test 3. Willingness to participate in the study 4. Covid 19 patients without underlying disease (in consultation with the consultant)
Criteria for not entering: 1. Breastfeeding and pregnancy 2. Advanced respiratory distress syndrome leading to intubation 3. Patients with coagulation disorders
Exclusion criteria: 1. Taking antioxidant supplements while studying 2. Incidence of coagulation disorders during the study

Intervention groups

Intervention group: includes 20 patients with COVID-19 who, in addition to their usual treatments, will take 3 capsules of 1000 mg omega-3 daily for 2 weeks (14 days). Control group: includes 20 patients with COVID-19 who, in addition to their usual treatments, will take 3 placebo capsules (liquid oil) daily for 2 weeks.

Main outcome variables

CRP;ESR:IL-6;CBC DIFF

General information

Reason for update

Greetings and courtesy, due to the decrease in the number of patients with covid-19, the decrease in the number of hospitalized patients and the lack of timely receipt of interventional supplements and placebos, I request that the age of patients be increased to 65 years and the end date of sampling be changed to 08/01/1401. Thank you for your efforts and cooperation.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210522051363N1**
Registration date: **2021-06-13, 1400/03/23**
Registration timing: **prospective**

Last update: **2022-07-22, 1401/04/31**

Update count: **1**

Registration date

2021-06-13, 1400/03/23

Registrant information

Name

Keianoush Karami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3233 2579

Email address

kianoushkarami91@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Omega-3 supplementation on Inflammatory biomarkers and total Blood cell counts of Patients with Covid-19

Public title
The effect of Omega-3 supplementation in Covid-19

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Being 20 to 65 years old Detection of COVID-19 based on PCR test Willingness to participate in the study Covid 19 patients without underlying disease (in consultation with the consultant)
Exclusion criteria:
Breastfeeding and pregnancy Advanced respiratory distress syndrome leading to intubation Patients with coagulation disorders

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method will be used so that 10 blocks of 4 people including 2 people in the intervention group and 2 people in the placebo group will be formed and assigned. The method of placing people in each block will be using a table of random numbers so In the table of random numbers from top to bottom, even numbers will be assigned to the intervention group and odd numbers to the placebo group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The treating physician and nurses are part of the uninformed study groups. The patient is unaware of the study groups. The researcher is unaware of the study groups. The data analyzer is unaware of the study groups. Assignment of patients in the drug and placebo groups is done by a nurse outside the above groups.

Placebo

Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Medical School Research - Tehran University of Medical Sciences
Street address
Keshavarz Boulevard, corner of Ghods, central headquarters of Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
3439123900

Approval date
2021-05-31, 1400/03/10

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.191

Health conditions studied

1

Description of health condition studied
Covid-19

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Serum levels of interleukin-6

Timepoint
Beginning and end of the study

Method of measurement
Blood test

2

Description
Serum levels of blood cells

Timepoint
Beginning and end of the study

Method of measurement
Blood test

3

Description

Serum levels of reactive protein-C

Timepoint

Beginning and end of the study

Method of measurement

Blood test

4

Description

Serum levels of erythrocyte sedimentation rate

Timepoint

Beginning and end of the study

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Includes 20 patients with COVID-19 who, in addition to their usual treatments, will take 3 1000 mg omega-3 capsules daily for 2 weeks (14 days).

Category

Treatment - Drugs

2

Description

Control group: Includes 20 patients with COVID-19 who, in addition to their usual treatments, will take 3 placebo capsules (liquid oil) daily for 2 weeks (14 days). Placebo capsules are very similar in appearance, color, smell and shape to omega-3 capsules.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Medical, Educational and Treatment Center

Full name of responsible person

Dr. Mona Talaschian

Street address

Iran, Tehran, North kargar, Shariati Medical, Educational and Medical Center

City

Tehran

Province

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1411713135

Phone

+98 21 8490 1000

Email

shariatihosp@tums.ac.ir

2

Recruitment center

Name of recruitment center

Shariati Medical, Educational and Medical Center

Full name of responsible person

Dr. Keivan Gohari Moghadam

Street address

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Email

shariatihosp@tums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mr. Dr. Sahraian

Street address

Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Vice Chancellor for Research and Technology «نماد «مورد تأیید انجمن»

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vcr@tums.ac.ir

Web page address

http://en.tums.ac.ir/en

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

Keianoush Karami

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Faculty of Nutrition and Dietetics, University of Medical Sciences and Health Services, Tehran, Keshavarz Blvd., Naderi St., Hojjatdoost Alley, No. 44

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Keianoush Karami

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

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City

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Postal code

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Phone

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Email

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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 information can be shared two months after the results are published.

When the data will become available and for how long

Two months after the publication of the results

To whom data/document is available

Doctors, nutritionists and nurses

Under which criteria data/document could be used

To evaluate other complementary therapies and compare its effect with existing therapies related to COVID-19 disease

From where data/document is obtainable

Send email to kianoushkarami91@gmail.com

What processes are involved for a request to access

data/document

Two months after the publication of the results, send a written request by e-mail to kianoushkarami91@gmail.com. In this case, and finally

up to one month after receiving the email, the request will be answered.

Comments