

# 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**

Tehran

##### **Postal code**

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**

Iran - Tehran - North Kargar - Shariati Medical, Educational and Medical Center

##### **City**

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##### **Province**

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##### **Phone**

+98 21 8490 1000

##### **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»

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

14155-6117

##### **Phone**

+98 21 8163 3685

##### **Email**

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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**Email**

kianoushkarami91@gmail.com

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

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Hossein Imani

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

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h-imani@sina.tums.ac.ir

**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**

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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**Postal code**

3439123900

**Phone**

+98 21 8895 5975

**Email**

kianoushkarami91@gmail.com

**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**