

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of omega-3 supplementation on inflammatory and biochemical markers in critical ill patients with COVID-19 a randomized clinical trial

#### Protocol summary

##### Study aim

Determining of the effect of omega-3 supplementation on inflammatory and biochemical markers in critical ill patients with COVID-19

##### Design

A randomized clinical trial study, triple-blind trial, fifty critical ill patients infected with COVID-19 undergoing respiratory and nutritional supports, Intervention and control groups through web-based randomization using <https://www.randomizer.org>, Twenty-five patients as the intervention group and other 25 patients as the control group.

##### Settings and conduct

we will attend at ICU of Razi hospital in Rasht, Iran, and complete the consent form, information will be required using these questionnaires: Medical history, Anthropometric measurement, Dietary intake, Biochemical & inflammatory indices (at baseline and after 14 days).

##### Participants/Inclusion and exclusion criteria

This study will be done on fifty critical ill patients with COVID-19 who are undergoing respiratory and nutritional supports in Razi hospital of Rasht, and enter to the study in the two intervention and control groups through simple randomized selection by web-based randomization.

##### Intervention groups

The intervention group will receive one capsule of omega-3 daily, produced by Omid persina damavand company, Iran (1000 mg Omega-3 for each capsule, containing of EPAs+DHAs), through adding supplement to the intestinal formula in the form of gavage. Specific intervention or activity don't perform in the control group and they only intake the same calorie as the intervention group using the same rout.

##### Main outcome variables

WBC, Neutrophils, Lymphocytes, LDH, CPK, CBC, CRP

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151226025699N3**

Registration date: **2020-05-20, 1399/02/31**

Registration timing: **prospective**

Last update: **2020-05-20, 1399/02/31**

Update count: **0**

##### Registration date

2020-05-20, 1399/02/31

##### Registrant information

##### Name

Saeid Doaei

##### Name of organization / entity

National Nutrition and Food Technology Research Institute

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6643 6744

##### Email address

sdoaei@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-04, 1399/03/15

##### Expected recruitment end date

2020-06-18, 1399/03/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of omega-3 supplementation on inflammatory and biochemical markers in critical ill patients with COVID-19 a randomized clinical trial

## Public title

The effect of omega-3 supplementation in COVID-19

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Written consent for participation Age over 34 years A diagnosis of COVID-19 based on symptoms such as severe pneumonia, fever, fatigue, dry cough, respiratory distress, and lungs involvement in the computed tomographic (CT) scan according to the doctor's confirmation

### Exclusion criteria:

Not tendency to continue participating in the study Diagnosed cardiovascular and lung diseases which can disturb the study process A diagnosis of malignant tumors Recent use of chemotherapy drugs Having incomplete medical records Non-compliance with the omega-3 supplementation Consumption of omega-3 fatty acids supplementation during the last 3-month before the study

## Age

From **35 years** old to **85 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: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Critical ill patients with COVID-19 who are undergoing respiratory and nutritional supports, will be assigned to the two intervention and control groups through simple individual randomized sampling by web-based randomization (randomizer.org). One of the researcher team determines the randomized allocation sequence using the computer program. The sealed non-transparent envelopes with randomized sequence will be used to hide the allocation.

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

This research is done in triple-blind method; This means that none of the patients, researchers and statistical analysts know the study arms. The patients in the study were not aware of the use or non-use of omega-3 supplements in this study. Omega-3 fatty acids are

added by a nurse, who is not on the research team, with a needle from omega-3 capsules to the gavage formula of the individuals in the case group, which has been informed confidential about them. The results are evaluated by a person outside the treatment team.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Sabzevar university of Medical sciences and Health services

##### Street address

Asad abadi street

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9617913112

#### Approval date

2020-05-17, 1399/02/28

#### Ethics committee reference number

IR.MEDSAB.REC.1399.054

## 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

White blood cells (WBCs)

#### Timepoint

Baseline, 14-day after intervention

#### Method of measurement

using standard kits and the researchers gather these information from the lab test section of the ICU sheets.

### 2

#### Description

Neutrophils

### **Timepoint**

Baseline, 14-day after intervention

### **Method of measurement**

using standard kits and the researchers gather these information from the lab test section of the ICU sheets.

### **3**

### **Description**

Lymphocytes

### **Timepoint**

Baseline, 14-day after intervention

### **Method of measurement**

using standard kits and the researchers gather these information from the lab test section of the ICU sheets.

### **4**

### **Description**

Lactate dehydrogenase (LDH)

### **Timepoint**

Baseline, 14-day after intervention

### **Method of measurement**

using standard kits and the researchers gather these information from the lab test section of the ICU sheets.

### **5**

### **Description**

Creatine phosphokinase (CPK)

### **Timepoint**

Baseline, 14-day after intervention

### **Method of measurement**

using standard kits and the researchers gather these information from the lab test section of the ICU sheets.

### **6**

### **Description**

Cell blood count (CBC)

### **Timepoint**

Baseline, 14-day after intervention

### **Method of measurement**

using standard kits and the researchers gather these information from the lab test section of the ICU sheets.

### **7**

### **Description**

C reactive protein

### **Timepoint**

Baseline, 14-day after intervention

### **Method of measurement**

using standard kits and the researchers gather these information from the lab test section of the ICU sheets.

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

### **Description**

Intervention group daily receive one capsule of omega-3 produced by Omid persina damavand company, Iran (1000 mg Omega-3 for each capsule, containing of EPAs+DHAs), through adding supplement to the intestinal formula in the form of gavage.

### **Category**

Treatment - Drugs

### **2**

### **Description**

Specific intervention or activity don't perform in the control group and they only intake the same calorie as the intervention group using the same rout.

### **Category**

Other

## **Recruitment centers**

### **1**

### **Recruitment center**

#### **Name of recruitment center**

Razi hospital

#### **Full name of responsible person**

Siamak Rimaz

#### **Street address**

RaziSardare Jangal Boulevard

#### **City**

Tehran

#### **Province**

Guilan

#### **Postal code**

41448

#### **Phone**

+98 13 3355 0028

#### **Email**

sdoaee@yahoo.com

## **Sponsors / Funding sources**

### **1**

### **Sponsor**

#### **Name of organization / entity**

Sabzevar University of Medical Sciences

#### **Full name of responsible person**

Dr. Alireza Moslem

#### **Street address**

Asad abadi street

#### **City**

Sabsevar

#### **Province**

Razavi Khorasan

#### **Postal code**

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#### **Phone**

+98 51 4401 1000

**Email**

info@medsab.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Sabsevar university of medical sciences

**Proportion provided by this source**

50

**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

**2**

**Sponsor**

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Dr. Arsalan salari

**Street address**

Parastar Street

**City**

Rasht

**Province**

Guilan

**Postal code**

41887-94755

**Phone**

+98 13 3334 6489

**Email**

salari@gums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Rasht university of medical sciences

**Proportion provided by this source**

50

**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**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Moslem

**Position**

Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Khorasan Razavi - Sabzevar - Asadabadi St. - Next to Melli garden- Central Headquarters Building - Fourth Floor Office Office

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9617913114

**Phone**

+98 51 4401 1004

**Email**

alirezamoslem@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Saeid Doaei

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Sardare Jangal Boulevard

**City**

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**Province**

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**Postal code**

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**Phone**

+98 13 3355 0028

**Email**

sdoaei@sbmu.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Saeid Doaei

**Position**

دکترای تخصصی

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Shahid Beheshti University of Medical Sciences,  
Tehran, IRAN.

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

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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