Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 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 Sabsevar 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

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Postal code

41448

Phone

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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

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Razavi Khorasan

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9617913112

Phone

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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

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Province

Guilan

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41887-94755

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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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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

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Rasht

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Guilan

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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
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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