

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of vitamin A, B, C, D, and E supplementations on biochemical parameters of critically ill patients with COVID-19: A randomized clinical trial

Protocol summary

Study aim

Determining the effect of vitamin A, B, C, D, and E supplementations on inflammatory and biochemical markers in critically ill patients with COVID-19

Design

Randomized clinical trial study, triple-blind trial, 135 critical ill COVID-19 patients undergoing respiratory & nutritional supports, Intervention & control groups via web-based randomization by <https://www.randomizer.org>, 45 patients as intervention group and other 90 as control group

Settings and conduct

Attending 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 (baseline & after 20 days)

Participants/Inclusion and exclusion criteria

Inclusion criteria: ICU patient of Razi hospital in Rasht; with Covid-19 diagnosis; under respiratory and intestinal nutrition support; written consent; age > 34-y; diagnosis of COVID-19 based on relevant symptoms; GCS score at least 3. Exclusion criteria: Not tendency to participate; having diseases that disrupt the study process; malignant tumors; recent chemotherapy drugs use; taking any of vitamin supplements during 3-month prior to study, history of allergy to vitamins, pregnancy.

Intervention groups

Intervention group will be received vitamin A, B, C, D, and E supplementations including vitamin A (50,000 dose/week), B complex (10 mg vitamin B1, 4 mg vitamin B2, 4 mg vitamin B6, 40 mg nicotinamide & 6 mg dexpantenol/day), C (500 mg/day), D (50,000 dose/day) and E (100 mg/day) from HAKIM Vitakim Pharmaceutical Company for 20-day by intestinal formula in gavage form. Specific intervention or activity don't perform in the

control group and only intake same calorie & route with intervention group

Main outcome variables

WBC, Neutrophils, Lymphocytes, LDH, CPK, CBC, CRP, PO2, PCO2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151226025699N5**

Registration date: **2021-04-07, 1400/01/18**

Registration timing: **prospective**

Last update: **2021-04-07, 1400/01/18**

Update count: **0**

Registration date

2021-04-07, 1400/01/18

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

2021-04-21, 1400/02/01

Expected recruitment end date

2021-05-11, 1400/02/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin A, B, C, D, and E supplementations on biochemical parameters of critically ill patients with COVID-19: A randomized clinical trial

Public title

The effect of vitamin A, B, C, D, and E supplementations in COVID-19

Purpose

Supportive

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 Awareness score of at least 3 based on the 15-point Glasgow Coma Score (GCS)

Exclusion criteria:

Not tendency to participate 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 vitamin A, B, C, D, and E supplementations Consumption of vitamin A, B, C, D, and E supplementations during the last 3-month before the study Pregnancy in women

Age

From **35 years** old to **85 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation will be done to two intervention and control groups by simple random sampling with individual randomization unit through the web-based application (<https://www.randomizer.org>). One of the members of the researcher team that not involved in the selection of samples, will determine the random allocation sequence using a computer program. Randomization tools are

sealed non-transparent envelopes that used in random sequences to hide the allocation.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This research is done in the 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 vitamin A, B, C, D, and E supplementations in this study. vitamin A, B, C, D, and E supplementations are added after 24 hours of hospitalization in the ICU for 20 days by a nurse, who is not on the research team, with a needle from supplementation 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

2021-03-15, 1399/12/25

Ethics committee reference number

IR.MEDSAB.REC.1399.195

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, 20-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, 20-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, 20-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, 20-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, 20-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, 20-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, 20-day after intervention

Method of measurement

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

8

Description

partial pressure of oxygen (PO2)

Timepoint

Baseline, 20-day after intervention

Method of measurement

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

9

Description

partial pressure of carbon dioxide

Timepoint

Baseline, 20-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

The intervention group in addition to receiving routine ICU medications according to the national protocol, which includes hydroxychloroquine sulfate, chloroquine phosphate, kaletra (lupinavir / ritonavir), ribavirin and atazanavir / ritonavir, will receive vitamin A, B, C, D, and E supplementations from HAKIM Vitakim Pharmaceutical Company including vitamin A (50,000 doses per week), B complex (including 10 mg of vitamin B1, 4 mg of vitamin B2, 4 mg of vitamin B6, 40 mg of nicotinamide and 6 mg of dexpantenol daily), C (dose 500 mg daily), D (50,000 daily dose) and E (100 mg daily dose) for 20 days through intestinal formula in the form of gavage.

Category

Treatment - Drugs

2

Description

The control group like the intervention group, receive routine ICU medications according to the national protocol, which includes hydroxychloroquine sulfate, chloroquine phosphate, kaletra (lupinavir / ritonavir), ribavirin and atazanavir / ritonavir. However, unlike them, no specific intervention or activity will be performed in the control group and they only intake the same calorie as the intervention group using the same route.

Category

Other

Academic

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Siamak Rimaz

Street address

Sardare Jangal Boulevard

City

Rasht

Province

Guilan

Postal code

41448

Phone

+98 13 3355 0028

Email

sdoae@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

9617913112

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

Sabzevar 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

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

City

Sabsevar

Province

Razavi Khorasan

Postal code

9617913114

Phone

+98 51 4401 1004

Email

alirezamoslem@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Saeid Doaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Sardare Jangal Boulevard

City

Rasht

Province

Guilan

Postal code

41448

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

Ph.D

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Shahid Beheshti University of Medical Sciences,
Tehran, IRAN.

City

Tehran

Province

Tehran

Postal code

009821

Phone

+98 21 6643 6744

Email

sdoaei@sbmu.ac.ir

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