Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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 dexpanthenol/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
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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 Sabsevar 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 dexpanthenol 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

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi hospital

Full name of responsible person
Siamak Rimaz

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Sardare Jangal Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Dr. Alireza Moslem

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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
Academic

2

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Dr. Arsalan Salari

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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

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Person responsible for scientific inquiries

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Assistant Professor

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Ph.D

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Other areas of specialty/work
Nutrition

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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