Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2021

Impact of vitamin B, A, D, E, C supplementation on improvement and mortality rate in patients with COVID-19 admitted in intensive care unit

Protocol summary

Study aim
The effect of supplementation with vitamins A, D, E, C, B on disease severity and mortality in patients with COVID-19

Design
A randomized, double-blind, placebo-controlled clinical trial

Settings and conduct
Only patients are unaware of the placement in the intervention or control group. Location: The intensive care unit is located at Imam Khomeini Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria : 1- Between 20 and 60 years old 2. Both men and women 3. The definitive or clinical diagnosis of COVID-19 4. Satisfaction with the study collaboration 5.BMI: 18.5-30 6. COVID-19 treatment protocol is almost identical in both groups 7- Patients not participating in other trials 8- No liver and kidney disorders Non-Entry Criteria: - Patients with rare and specific viral diseases such as HIV - Patients undergoing chemotherapy over the past month - Any other condition that the specialist diagnoses is very specific.

Intervention groups
Patients were divided into intervention and control groups. Intervention group supplemented with vitamin D at 25,000 international units of vitamin A daily, 600,000 international units of vitamin D once daily, 300 units of vitamin E twice daily, 500 mg Vitamin C is taken 4 times a day and finally B vitamins are taken as a daily solute ampoule. The control group received no supplement or placebo.

Main outcome variables
Variables: 1- Weight, height and BMI of patients 2. Severity of pulmonary involvement according to CT scan 3. Respiratory support (Insive or Non-Invasive) 4% oxygen saturation 5- Serum levels of WBC, CRP, IL6, TNF-α, IFN-G, ESR 6. The patient's body temperature 7. The presence or absence of involvement of other organs 8- Duration of hospitalization 9. Mortality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200319046819N1**
Registration date: **2020-04-04, 1399/01/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-04, 1399/01/16**
Update count: **0**

Registration date
2020-04-04, 1399/01/16

Registrant information

Name
Sama Bitarafan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6694 8899

Email address
bitarafans@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-02, 1399/01/14

Expected recruitment end date
2020-07-04, 1399/04/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Impact of vitamin B, A, D, E, C supplementation on improvement and mortality rate in patients with COVID-19 admitted in intensive care unit

Public title
supplementation in COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 and 60 years Both males and females COVID-19 clinical or definitive diagnosis Satisfaction with the study patient do not participate in other trial designs BMI: 18.5-30 - Lack of renal and hepatic abnormalities
Exclusion criteria:
Patients with specific and rare viral diseases such as HIV etc. Patients have been undergoing chemotherapy for the past month Any other patients that the specialist knows to be unique.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
blocking randomization
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients are unaware of being placed in the intervention or control group after declaration of consent. All treatment staff are aware of the patients in which group due to the specific conditions of the ICU and the absence of placebo for control group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Committee on Ethics in Tehran university of medical sciencies
Street address
Block A, Central Headquarters of Ministry of Health and Medical Education, Iran Sima Street, between South Flamak and Zarafshan, Qods Town (West), Tehran,
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2020-04-01, 1399/01/13
Ethics committee reference number
IR.TUMS.VCR.REC.1399.090

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19

Primary outcomes

1

Description
WBC, CRP, IL6,TNF-α, IFN-G ، ESR
Timepoint
Before and after intervention
Method of measurement
Laboratory blood test

2

Description
Intensity of pulmonary involvement
Timepoint
Before and after intervention
Method of measurement
CT scan

3

Description
Mortality
Timepoint
Before and after intervention
Method of measurement
Observation

Secondary outcomes

1

Description
Body Mass Index
Timepoint
Before and after intervention

Method of measurement
Measuring weight and height and using the formula

2

Description
Duration of hospitalization
Timepoint
Before and after intervention
Method of measurement
Observation

3

Description
Saturation percentage of blood oxygen
Timepoint
Before and after intervention
Method of measurement
Oxymeter

Intervention groups

1

Description
Intervention group: Vitamin supplementation in order (ampoules): 25,000 international units of vitamin A daily, 600,000 international units of vitamin D once during the intervention time, 300 international units of vitamin E, 2 times a day, 500 mg of vitamin C, 4 times a day and B vitamins in the form of one Soluvit ampoule in a day. The control group does not receive any supplement or placebo. In this study, the duration of supplementation and evaluation of patients is one week .Except for Soluvit (Fresenius Kabi New Zealand) , all supplements are made in Iran. Soluvit: Thiamine nitrate 3.1 mg, Sodiumriboflavine phosphate 4.9 mg(corresponding to Vitamin B2 3.6mg), Nicotinamide 40 mg,Pyridoxine hydrochloride 4.9 mg(corresponding to Vitamin B6 4.0mg), Sodium pantothenate 16.5 mg(corresponding to Pantothenic acid15 mg), Sodium ascorbate 113 mg(corresponding to Vitamin C 100mg), Biotin 60 µg, Folic acid 400 µg,Cyanocobalamin 5 µg,
Category
Treatment - Drugs

2

Description
Control group: no placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Intensive Care Unit
Full name of responsible person
Sama Bitarafan
Street address
Intensive Care Unit of open heart, Imam Khomeini Hospital, Keshavarz Blvd, Tehran
City
Tehran
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Bitarafans@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
Street address
central university building, corner of Quds Street, Keshavarz Boulevard, Tehran
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 4208
Email
rcco@tums.ac.ir
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
Sama Bitarafan

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Floor 4, Iranian Center of Neurological Research biulding, Imam Khomeini Hospital, Keshavarz Blvd, Tehran

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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
Not applicable

Data Dictionary
Not applicable