

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 (Invasive 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 sciences

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

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Email

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

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Tehran

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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
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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