Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of vitamin D and magnesium supplementation on clinical symptoms, inflammatory markers and oxidative stress in patients with COVID-19: double-blind randomized control clinical trial

Protocol summary

Study aim

This study aims to evaluate the effect of vitamin D and magnesium supplementation on clinical symptoms, inflammatory markers, and oxidative stress in patients with Covid-19.

Design

This study is a double-blind clinical trial with a factorial design and the intervention period will be 3 weeks. The participants will be divided into four groups of 26 people and a random block design will be used for randomization.

Settings and conduct

This study will be conducted on 104 people aged 18 to 65 with Covid-19 admitted to the Shahid Mohammadi hospital in Bandar Abbas city that be eligible for inclusion in the study.

Participants/Inclusion and exclusion criteria

People aged 18-65, confirmation of Covid-19 by RT-PCR test, completing informed consent, less than 48 hours have passed since the patient was hospitalized, no skin or gastrointestinal allergies due to taking multivitamin supplements, vitamin D, and magnesium, people with more than 30 breaths per minute and less than 93% oxygen saturation in room air and sea level.

Intervention groups

A) Vitamin D (two 50,000 IU capsules at the beginning of the study, two 50,000 IU capsules on the 4th day, one 50,000 IU capsule on the 11th day, and one 50,000 IU capsule on the 17th day) and magnesium supplement (300 mg/day). B) Vitamin D supplement and magnesium placebo. C) Magnesium supplement and vitamin D placebo. D) Vitamin D placebo and magnesium placebo.

Main outcome variables

Clinical outcomes (fever, dry cough, shortness of breath, headache, myalgia, and oxygen saturation) and laboratory markers (MDA, TAC, WBC, neutrophils count, lymphocytes count, levels of 25 hydroxyvitamin D and magnesium)

General information

Reason for update

In the section of randomization description, the order of codes A, B, C, and D in a number of blocks are not written correctly, which need to be edited and corrected.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210702051763N1**
Registration date: **2021-08-14, 1400/05/23**
Registration timing: **prospective**

Last update: **2022-05-07, 1401/02/17**
Update count: **2**

Registration date

2021-08-14, 1400/05/23

Registrant information

Name

Nahid Ramezani-Jolfaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3371 0373

Email address

ramezani-jolfaie@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D and magnesium supplementation on clinical symptoms, inflammatory markers and oxidative stress in patients with COVID-19: double-blind randomized control clinical trial

Public title

The effect of vitamin D and magnesium supplementation on patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People aged 18-65 confirmation of Covid-19 infection by RT-PCR test completing informed consent less than 48 hours have passed since the patient was hospitalized no skin or gastrointestinal allergies due to taking multivitamin supplements, vitamin D, and magnesium people with more than 30 breaths per minute and less than 93% oxygen saturation in room air and sea level.

Exclusion criteria:

Pregnancy or lactation take a daily multivitamin or take a vitamin D or magnesium supplement in the last month participating in other clinical studies renal failure or dialysis, severe liver disease or cirrhosis known diagnosis of hypercalcemia patients who discharged from the hospital less than 24 hours after the start of the intervention history of kidney stones in the last year transfer the patient to the ICU baseline vitamin D levels above 80 ng/ml baseline magnesium levels above 2.6 mg/dl.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a random block design will be used for randomization. In this way, 24 blocks of 4 will be made using codes A, B, C, and D that these blocks will be numbered from 1 to 24 (ABCD, ACBD, ABDC, ADBC, ACDB, ADCB, BACD, BCAD, BADC, BDAC, BCDA, BDCA, CABD, CBAD, CADB, CDAB, CBDA, CDBA, DABC, DBAC, DACB, DCAB, DBCA, DCBA) and then using R software, twenty-six blocks from blocks 1 to 24 are randomly selected.

Blinding (investigator's opinion)

Double blinded

Blinding description

Vitamin D supplement and placebo will be provided by Zahravi Pharmaceutical Company (Iran). Magnesium placebo will be made from starch with the same color and shape as the magnesium supplement by the Faculty of Pharmacy of Hormozgan University of Medical Sciences. In this study, blinding of participants, staff, and investigators will be done (Magnesium and Vitamin D supplements and placebos will be placed in the same package with codes of A, B, C, and D by a responsible person who is not aware of the study objectives. The codes will not be available to researchers until after statistical analysis. In order to blind the participants, they will be explained at the beginning of the study who will receive one of four types of intervention and will not be told the exact type of supplement.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Hormozgan University of Medical Sciences

Street address

Imam Hussein Blvd, Campus of Medical Sciences

City

Bandar Abbas

Province

Hormozgan

Postal code

7919693116

Approval date

2021-05-30, 1400/03/09

Ethics committee reference number

IR.HUMS.REC.1400.085

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
Myalgia
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
to be or not to be

2

Description
fever
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
to be or not to be

3

Description
dry cough
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
to be or not to be

4

Description
Shortness of breath
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
to be or not to be

5

Description
Percentage of oxygen saturation
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
Oxygen meter

6

Description
WBC
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
Laboratory tests

7

Description
CRP
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
Laboratory tests

8

Description
MDA
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
Laboratory tests

9

Description
TAC
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
Laboratory tests

10

Description
Headache
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
to be or not to be

11

Description
mortality
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
number

12

Description
Neutrophil count
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
number

13

Description
Lymphocyte count
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
number

14

Description
The ratio of neutrophils to lymphocytes
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
Percentage

15

Description
25 hydroxyvitamin D
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
Nanograms per milliliter

16

Description
magnesium
Timepoint
at baseline and at the end of study (3 weeks later)
Method of measurement
milligram per deciliter

Secondary outcomes

empty

Intervention groups

1

Description
vitamin D supplement (two 50,000 IU capsules at the beginning of the study, two 50,000 IU capsules on the 4th day, one 50,000 IU capsule on the 11th day, and one 50,000 IU capsule on the 17th day) and magnesium supplement (300 mg/day).
Category
Treatment - Drugs

2

Description
vitamin D (two 50,000 IU capsules at the beginning of the study, two 50,000 IU capsules on the 4th day, one 50,000 IU capsule on the 11th day, and one 50,000 IU capsule on the 17th day) and magnesium placebo
Category
Treatment - Drugs

3

Description
Magnesium supplement (300 mg/day) and vitamin D placebo
Category
Treatment - Drugs

4

Description
Vitamin D placebo and magnesium placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mohammadi Hospital, affiliated to Hormozgan University of Medical Sciences
Full name of responsible person
Mohammad Mohammadi
Street address
Imam Hussein Blvd, Campus of Medical Sciences
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mohammadi.nut@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Teamur Aghamolaei
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Imam Hussein Blvd, Campus of Medical Sciences
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Postal code
7919693116
Phone
+98 76 3371 0393
Email
teaghamolaei@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences

Full name of responsible person
Nahid Ramezani-Jolfaie

Position
Assistant Professor of Nutritional Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available