

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Aug 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

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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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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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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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Name of organization / entity

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Other areas of specialty/work

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Postal code

7919693116

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