

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effect of vitamin D supplementation in diagnosed cases of 2019 Novel Coronavirus; a randomized clinical trial

Protocol summary

Study aim

Assessment of the effect of vitamin D supplementation among patients with the diagnosis of 2019 Novel Coronavirus infection

Design

Clinical trial containing group control, with parallel groups, double blind, randomized, third phase on 210 patients. Block method will be used for randomization.

Settings and conduct

Interventions in three groups will be performed as below:
Group 1: 50000 International Unit (IU) vitamin D supplementation and then 10000 IU supplementation daily
Group 2: 1000 IU vitamin D supplementation daily
Blood samples will be taken before and after the intervention. This study will be done in Mashhad-Iran.
Blinding will be performed for patients and investigators.

Participants/Inclusion and exclusion criteria

Age 30- 60 years old; serum vitamin D level lower than 30 nano gram per milliliter; cases who diagnosed as COVID-19 infection by clinical features; laboratory findings (positive C Reactive Protein, lymphocyte lesser 1100 per milliliter); serum vitamin D level upper than 30 nanogram per milliliter; use of vitamin supplements; use of immune suppressants or medications that interfere with vitamin D metabolism; history of nephrolithiasis; kidney disorders requiring dialysis or current malignancy diagnosis; pregnancy or lactating.

Intervention groups

The 50000 International Unit (IU) vitamin D supplement weekly and then 10000 IU vitamin D supplement daily and the 1000 IU vitamin D supplement daily

Main outcome variables

Chest X-ray findings, CT scan findings, Length of stay, Serum vitamin D level, Serum C-Reactive Protein level, Serum Erythrocyte Sedimentation Rate level, Serum neutrophil to lymphocyte ratio, Fasting Blood Glucose, Low Density Lipoprotein, High Density Lipoprotein, Triglycerid, Total cholesterol

General information

Reason for update

Due to the decrease in the number of study groups, the number of sample sizes for the study was changed to 140 according to the new calculations.

Acronym

IRCT registration information

IRCT registration number: **IRCT20110726007117N11**
Registration date: **2020-07-05, 1399/04/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-06, 1400/04/15**

Update count: **1**

Registration date

2020-07-05, 1399/04/15

Registrant information

Name

Majid Ghayour Mobarhan

Name of organization / entity

Mashhad University of Medical Sciences,

Country

Iran (Islamic Republic of)

Phone

+98 51 1822 8573

Email address

ghayourm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D supplementation in diagnosed cases of 2019 Novel Coronavirus; a randomized clinical trial

Public title

Effect of vitamin D supplementation in novel corona virus 2019

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 30- 60 years old Serum Vitamin D level lower than 30 nanograms per milliliter Cases who diagnosed as novel coronavirus 2019 infection by clinical features (sore throat, dry cough, dyspnea), laboratory findings (positive C- Reactive protein, lymphocyte<1100 per milliliter), or radiological findings (lung patchy infiltrations in chest X-ray or CT scan)

Exclusion criteria:

Serum Vitamin D level upper than 30 nanograms per milliliter Use of medications that interfere with vitamin D metabolism History of hypercalcemia, kidney disorders, cirrhosis

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

The eligible participants will undergo individual block randomization according to sex status with the use of block size of three. For this randomization, we will use solid blurred envelopes containing A or B or C labels.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding will be performed in two levels of patients and investigators (double blind)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Faculty of Medicine, Mashhad University of Medical Sciences Campus, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948546

Approval date

2020-05-09, 1399/02/20

Ethics committee reference number

IR.MUMS.REC.1399.237

Health conditions studied

1

Description of health condition studied

Covid-19 disease

ICD-10 code

U07.1

ICD-10 code description

Use this code when COVID-19 has been confirmed by laboratory testing irrespective of severity of clinical signs or symptoms. Use additional code, if desired, to identify pneumonia or other manifestations.

Primary outcomes

1

Description

C-Reactive Protein level

Timepoint

Measurement of C-Reactive Protein level before starting intervention and 30 days after starting the intake of vitamin D supplementation

Method of measurement

enzyme-linked immunosorbent assay kit

Secondary outcomes

1

Description

Erythrocyte Sedimentation Rate level

Timepoint

Measurement of Erythrocyte sedimentation level before starting intervention and 30 days after starting the intake of vitamin D supplementation

Method of measurement

Westergren method

2

Description

neutrophil to lymphocyte ratio level

Timepoint

Measurement of neutrophil to lymphocyte ratio level before starting intervention and 30 days after starting the intake of vitamin D supplementation

Method of measurement

microscopic count

3

Description

Serum vitamin D level

Timepoint

Measurement of serum vitamin D level before starting intervention and 30 days after starting the intake of vitamin D supplementation

Method of measurement

Enzyme-linked immunosorbent assay

4

Description

Low Density Lipoprotein Level

Timepoint

Measurement of Low Density Lipoprotein level before starting intervention and 30 days after starting the intake of vitamin D supplementation

Method of measurement

Direct detergent method

5

Description

High Density Lipoprotein Level

Timepoint

Measurement of High Density Lipoprotein level before starting intervention and 30 days after starting the intake of vitamin D supplementation

Method of measurement

Direct detergent method

6

Description

Total cholesterol level

Timepoint

Measurement of total cholesterol level before starting intervention and 30 days after starting the intake of vitamin D supplementation

Method of measurement

Direct detergent method

7

Description

Triglyceride level

Timepoint

Measurement of tryglyserid level before starting intervention and 30 days after starting the intake of vitamin D supplementation

Method of measurement

Direct detergent method

8

Description

Fasting Blood Glucose level

Timepoint

Measurement of Fasting Blood Glucose level before starting intervention and 30 days after starting the intake of vitamin D supplementation

Method of measurement

Enzymatic colorimetric method

Intervention groups

1

Description

Intervention group: 50000 International Unit (IU) pearl vitamin D as single dose, made in ZAHRAVI manufacture and then 10000 IU vitamin D syrup , 30 days, with lunch, Made in the department of Pharmacology Mashhad University of Medical Sciences

Category

Treatment - Drugs

2

Description

Control group: 1000 International Unit (IU) syrup vitamin D daily, 30 days, with lunch, Made in the department of Pharmacology Mashhad University of Medical Sciences

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Doctor Majid Ghayour Mobarhan

Street address

Faculty of Medicine, Mashhad University of Medical Sciences Campus, Azadi Square

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Ghayourm@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Doctor Mohsen Tafaghodi

Street address

Faculty of Medicine, Mashhad University of Medical Sciences Campus, Azadi Square

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tafaghodiM@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Doctor Majid Ghayour Mobarhan

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Email

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Doctor Majid Ghayour Mobarhan

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Khorasanchi

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

Nutrition

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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

All patients' identical information will be confidential and were not published anywhere.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The study protocol will be published and available to

researchers after the study is completed. Statistical analysis and clinical reports of individuals will be available to researchers in the form of articles resulting from the project.

When the data will become available and for how long

Initial access to protocols and articles from 1400

To whom data/document is available

Academic and scientific researchers could apply.

Under which criteria data/document could be used

Scientific articles can be used by researchers.

From where data/document is obtainable

To receive the articles, contact the following e-mail address: Ghayourm@mums.ac.ir

What processes are involved for a request to access data/document

If articles and protocols are published, they can be emailed.

Comments