Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Oct 2020

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 weekly Group 2: 5,000 IU vitamin D supplementation daily Group 3: 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, the 5000 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, Triglyserid, Total cholesterol

General information

Reason for update

Acronym

IRCT registration information

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

Last update: **2020-07-05, 1399/04/15**
Update count: **0**

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

recruiting

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 mililiter), 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: **210**

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 envelops containing A or B or C labels.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding will be perfomed 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
Ḍoctor Majid Ghayour Mobarhan
Street address
Faculty of Medicine, Mashhad University of Medical Sciences Campus, Azadi Square
City
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Postal code
9177948546
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+98 51 3800 2420
Email
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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Email
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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Faculty of Medicine, Mashhad University of Medical Sciences Campus, Azadi Square

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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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Email
Khorasanchiz981@mums.ac.ir

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