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, Triglycerid, 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 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: 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 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
**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

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**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

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**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

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**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

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**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

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**Description**
Triglyceride level

**Timepoint**
Measurement of triglyceride level before starting intervention and 30 days after starting the intake of vitamin D supplementation

**Method of measurement**
Direct detergent method

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**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

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**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

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**Recruitment centers**

1. **Recruitment center**
   Name of recruitment center
   Shariati hospital

   **Full name of responsible person**
   Doctor Majid Ghayour Mobaran

   **Street address**
   Faculty of Medicine, Mashhad University of Medical Sciences Campus, Azadi Square

   **City**
   Mashhad

   **Province**
   Razavi Khorasan

   **Postal code**
   9177948546

   **Phone**
   +98 51 3800 2420

   **Email**
   Ghayourm@mums.ac.ir

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**Sponsors / Funding sources**
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
Street address  
Faculty of Medicine, Mashhad University of Medical Sciences Campus, Azadi Square
City  
Mashhad
Province  
Razavi Khorasan
Postal code  
9177948546
Phone  
+98 51 3800 2420
Email  
Ghayourm@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity  
Mashhad University of Medical Sciences
Full name of responsible person  
Doctor Mohsen Tafaghodi
Position  
Doctor
Latest degree  
Ph.D.
Other areas of specialty/work  
Nutrition
Street address  
Faculty of Medicine, Mashhad University of Medical Sciences Campus, Azadi Square
City  
Mashhad
Province  
Razavi Khorasan
Postal code  
9177948546
Phone  
+98 51 3841 2081
Email  
tafaghodiM@mums.ac.ir

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
Street address  
Faculty of Medicine, Mashhad University of Medical Sciences Campus, Azadi Square
City  
Mashhad
Province  
Razavi Khorasan
Postal code  
9177948546
Phone  
+98 51 3800 2420
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