Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2021

Investigating preventive effects of oral 25-hydroxyvitamin D3 on COVID-19 in adults: A Randomized, Controlled Double-Blind Clinical Trial.

Protocol summary

Study aim

1. To determine the effect of oral supplementation by 25(OH)D on serum levels of 25(OH)D and relate this to decrease the incidence of Coronavirus infection in health providers and family members of COVID-19 patients 2. To determine the effect of oral supplementation by 25(OH)D on serum levels of 25(OH)D and relate this to the primary and secondary outcomes of Coronavirus infection in newly affected patients.

Design

A double-blind, randomized controlled trial

Settings and conduct

The project will perform in as COVID-19 centers affiliated to the Tehran University of medical sciences. Subjects include health providers and the patients' relatives with negative COVID-19. Subjects will be allocated to the intervention or placebo groups. The coordinator will determine this with a computer-generated randomization program. The coordinator does not involve the treatment process and data gathering and data analysis. Participants, physicians, data collectors, and project executives are blind to the type of medication (intervention and placebo). Each patient has a specific code. Based on the drug coding, the physician or researcher will provide the drug to the subjects.

Participants/Inclusion and exclusion criteria

Inclusion criteria: not affected by COVID-19 (based on WHO criteria) Exclusion criteria: Ongoing treatment with vitamin D metabolites or analogs or consuming medication affecting bone metabolism History of chronic disorders Inability to give informed consent

Intervention groups

Subjects in the intervention group will receive 1000 IUs of 25(OH)D daily for 8 wks and controls will receive placebo daily for 8 wks.

Main outcome variables

1. The number of new cases with COVID-19 2.Duration of infection 3.Dyspnea experience 4.Duration of hospitalization 5.Admitted to ICU: duration 6.Incubation period 7.Lymphopenia 8.Mortality during 60 days of study

General information

Reason for update

In section Sharing plan: The item "no plan" was changed to "Yes - there is a plan to make this available"

Acronym

IRCT registration information

IRCT registration number: **IRCT20200401046909N2**
Registration date: **2020-04-11, 1399/01/23**
Registration timing: **prospective**

Last update: **2020-05-27, 1399/03/07**
Update count: **2**

Registration date

2020-04-11, 1399/01/23

Registrant information

Name

Zhila Maghbooli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6670 6142

Email address

zhilayas@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-14, 1399/01/26

Expected recruitment end date

2020-10-30, 1399/08/09

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating preventive effects of oral 25-hydroxyvitamin D3 on COVID-19 in adults: A Randomized, Controlled Double-Blind Clinical Trial.

Public title
Evaluation of the efficacy of oral 25-hydroxyvitamin D3 on COVID-19
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Non-infected with COVID-19 (based on WHO criteria) Older than 17 years old and younger than 76 years old No medications or disorders that would affect vitamin D metabolism Women must be not pregnant at baseline and during study Ability and willingness to give informed consent and comply with protocol requirements
Exclusion criteria:
Ongoing treatment with pharmacologic doses of vitamin D, vitamin D metabolites or analogs Pregnant or lactating women Severe underlying diseases, such as an advanced malignant tumor, end-stage lung disease, etc. History of elevated serum calcium levels more than 10.6 mg/dl History of chronic hepatic, renal failure or patients with reduced kidney function, cancers, malabsorption syndrome, or granulomatous disorders such as Sarcoidosis or Tuberculosis Supplementation with over the counter formulations of vitamin D2 or vitamin D3 Use of tanning bed or artificial UV exposure within the last two weeks Consuming medication affecting bone metabolism (anti-convulsants, anti-tuberculosis medication, cimetidine, theophylline, and cholestyramine) Following special diets such as vegetarian diet or consuming fortified products regularly A history of an adverse reaction to orally administered vitamin D, vitamin D metabolites or analogs Inability to give informed consent
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **540**
Randomization (investigator's opinion)
Randomized
Randomization description
in this study, the random allocation for intervention and placebo groups is based on a "Random Allocation Software". A simple randomized list will be produced by the software for a sample size of 540 subjects into two groups of the intervention and placebo with equal sample size and numeric sequential unique.
Blinding (investigator's opinion)
Double blinded
Blinding description
It is a double-blind clinical trial. Participants, physicians, data collectors, and project executives are blind to the type of medication (medication and placebo). The drug and placebo are coded by someone else. This person has no role in treatment, data collection and data analysis. The codes are randomly selected for each participant. Each patient has a specific code. Based on the drug coding, the physician or researcher will provide the drug to the participants. medication: containing 25OHD soft gelatin capsular placebo: containing white to off white color suspension oil
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Research deputy of Tehran University of Medical Sciences, Qods building, Qods St. Cross, Keshavarz Blvd
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Tehran
Province
Tehran
Postal code
1416753955
Approval date
2020-03-17, 1398/12/27
Ethics committee reference number
IR.TUMS.VCR.REC.1399.061

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
SARS-associated coronavirus as the cause of diseases

classified elsewhere

Primary outcomes

1

Description
Affected by COVID-19
Timepoint
Sign of COVID-19 during study
Method of measurement
patients over 18 years of age with acute respiratory tract infection symptoms (e.g. fever, cough, dyspnea) with no other etiology that fully explains the clinical presentation accompanied by chest computed tomography (CT) scan findings compatible with Covid-19 or definite diagnosis of Covid-19 with real-time polymerase chain reaction (PCR)

Secondary outcomes

1

Description
Infection duration
Timepoint
During study
Method of measurement
WHO criteria

2

Description
Severity of disease (mild, moderate, sever)
Timepoint
During study
Method of measurement
Dyspnea, Palsoximethry result, CBC diff, Blood gas parameters, and acid-base, CT scan result

3

Description
Serum levels of Vitamin D
Timepoint
Before intervention, end of 4th and end of 8th intervention
Method of measurement
HPLC

Intervention groups

1

Description
Intervention group: containing 25OHD soft gelatin capsular 1000 IU , Producer: Dishmen. the case group will receive 1000 IUs of 25(OH)D daily for 8 wks. The subjects will receive a bottle containing 30 capsules in first and second visits that will contain the 25(OH)D. The bottles will be returned to be checked at each visit.
Category
Prevention

2

Description
Placebo: containing white to off white color suspension oil. Producer: Dishmen Company. The control group will receive placebo daily for 8 wks..The subjects will receive a bottle containing 30 capsules in first and second visits that will contain the placebo. The bottles will be returned to be checked at each visit.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam khomeini
Full name of responsible person
Zhila Maghbooli
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Recruitment center
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3

Recruitment center
Name of recruitment center
PAkdasht Hospital
Full name of responsible person

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4

Recruitment center
Name of recruitment center
Ziaian Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Mohammad ali Sahraian
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Qods St, Keshavarz Bulv.
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tums_edu@tumc.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Zhila Maghbooli
Position
Assistant Professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Manuscripts will be published based on the project data

When the data will become available and for how long

End of study

To whom data/document is available

For all researchers and clinicians

Under which criteria data/document could be used

Based on the Iran Ministry of Health condition related to clinical trials

From where data/document is obtainable

Deputy of Research and Technology, Tehran University of Medical Sciences, Tehran, Iran

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

There is no further information.

Comments