

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

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

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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

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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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Full name of responsible person

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Recruitment center

Name of recruitment center

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Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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
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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