Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The efficacy of oral 25-hydroxyvitamin D3 on COVID-19 treatment in adults: A Randomized, Controlled Double-Blind Clinical Trial.

Protocol summary

Study aim
to determine the effect of oral 25(OH)D on serum levels of 25(OH)D and association to the primary and secondary outcomes of COVID-19 infection in affected patients.

Design
double blind, randomised controlled trial

Settings and conduct
The project will perform in Sina hospital as a COVID-19 center. Subjects including patients with positive COVID-19 Participants, physicians, data collectors, and project executives are blind to the type of medication (medication and placebo). The coordinator will determine this with a computer-generated randomization program. Each patient has a specific code. Based on the drug coding, the physician or researcher will provide the drug to the participant.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. COVID-19 positive in the patient group Exclusion criteria: 1.Ongoing treatment with vitamin D metabolites or analogs or consuming medication affecting bone metabolism 2.History of chronic disorders such as hepatic or renal failure, malabsorption syndrome 3.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
Duration of infection Dyspnea experience duration of hospitalization Admitted to ICU: duration Incubation period Lymphopenia Mortality during 60 days of study

General information

Reason for update
In section Sharing plan: The item "Undecided" was updated to "Yes - there is a plan to make this available"

Acronym

IRCT registration information
IRCT registration number: **IRCT20200401046909N1**
Registration date: **2020-04-09, 1399/01/21**
Registration timing: **prospective**

Last update: **2020-06-01, 1399/03/12**
Update count: **2**

Registration date
2020-04-09, 1399/01/21

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
2020-04-15, 1399/01/27

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
The efficacy of oral 25-hydroxyvitamin D3 on COVID-19 treatment in adults: A Randomized, Controlled Double-Blind Clinical Trial.

Public title
Evaluation of the efficacy of oral 25-hydroxyvitamin D3 on COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
2019-nCov (SARA-Cov-2) nucleic acid positive will be detected by PCR in affected patients 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 analogues Pregnant or lactating women; Severe underlying diseases, such as advanced malignant tumor, end-stage lung disease, etc. History of elevated serum calcium >9.8 mg/dl) Chronic hepatic or renal failure or patients with reduced kidney function, cancers, and malabsorption syndrome, a 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), as well as those who are following special diets such as vegetarian diet or consuming fortified products regularly. Subjects with a history of an adverse reaction to orally administered vitamin D, vitamin D metabolites or analogues. 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: **260**
Randomization (investigator's opinion)
Randomized
Randomization description
In this clinical trial, 260 patients with positive COVID-19 will be recruited. Patients will be randomly allocated to the drug group (N=130) and placebo group (N=130). The randomization method is "restricted randomization". It will be determined by a "Random Allocation Software". Subjects in the drug group will receive 1000 IUs of 25(OH)D daily for 8 wks and subjects in the placebo group will receive placebo daily for 8 wks.
Blinding (investigator's opinion)
Double blinded
Blinding description
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
infection duration
Timepoint
during study
Method of measurement
WHO criteria

Secondary outcomes

1

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

2

Description
serum levels of Vitamin D
Timepoint
before intervention, end of 4th and end of 8th intervention
Method of measurement
HPLC method

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
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Mohammadali Sahraian
Street address
Emamkhomeini St., Hasanabad Sq.
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Recruitment center
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3

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Name of recruitment center
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5

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Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammadali Sahraian, Research Deputy
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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
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

the primary outcome measures

When the data will become available and for how long

six months after publishing paper/ until 2 years after the end of the study

To whom data/document is available

Based on the Iran Ministry of a health condition related to clinical trials

Under which criteria data/document could be used

Based on Iran Ministry of Health condition related to clinical trials

From where data/document is obtainable

the email address of the principal investigator

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

The request will be reviewed by the project executors and then Deputy of Research and Technology, Tehran University of Medical Sciences, Tehran, Iran.

Comments