

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation effect of treatment with IM(intramuscular) D3 on clinical, paraclinical symptoms and signs and in-hospital outcome at patient admitted with coovid19

Protocol summary

Study aim

Determination of the effect of vitamin D level on the status of clinical symptoms and laboratory and radiological findings and short-term results of patients with COVID-19

Design

This study is performed as a clinical trial with a control group, with parallel, 3-blind, randomized groups (block method with a volume of 4 was used to determine the sequence of allocation) and with a sample size of 100 people in the first phase. First, everyone fills out the checklist. Allocation sequences that are placed in each envelope and placed next to each other in order and patients open an envelope in order and understand their group (group A or B)

Settings and conduct

This study is performed on COVID-19 patients with vitamin D deficiency in the COVID-19 ward of Imam Hossein Shahroud Hospital in two groups of testing and control. Individuals in the testing group undergo a treatment protocol to increase vitamin D, and the control group did not receive any intervention. Then, at the end of the hospitalization court, both groups are evaluated. Each patient knows in which group they are (A or B) but does not know which group receives the intervention. Also, the information collector, information analyst, and laboratory manager do not know which intervention group to receive.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individual satisfaction to participate in the project, Confirmation of COVID-19 disease by CPR test, Non-entry criteria: Vitamin D levels more than thirty nanograms per millilitre

Intervention groups

Test group: intramuscularly Injections of 300 mg of vitamin D at the beginning of the first week, as well as another dose at the beginning of the second week.

Control group: No intervention.

Main outcome variables

Clinical course, paraclinical, in-hospital outcome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200411047024N1**

Registration date: **2020-04-29, 1399/02/10**

Registration timing: **prospective**

Last update: **2020-04-29, 1399/02/10**

Update count: **0**

Registration date

2020-04-29, 1399/02/10

Registrant information

Name

Hossein Sheibani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 23 3239 2820

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sheybani@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation effect of treatment with IM(intramuscular) D3 on clinical, paraclinical symptoms and signs and in-hospital outcome at patient admitted with coovid19

Public title

Evaluation effect of treatment with IM D3 on clinical, paraclinical symptoms and signs and inhospital outcome at patient admitted with coovid19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Individual satisfaction to participate in the project

Confirmation of covid-19 disease by CPR test

Exclusion criteria:

Vitamin D levels are more than 30 Nanograms /milliliter

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

The allotment sequence is determined using the website. Block method 4 was used to determine the allocation sequence. White envelopes are used to hide the allocation sequence. In this way, each sequence is placed inside a white envelope and the envelopes are arranged side by side and we number the letters to don't be disorganized. For each eligible participant, an envelope will be opened and assigned to the desired group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

White envelopes are used to hide the allocation sequence. In this way, each sequence is placed inside a white envelope and the envelopes are arranged side by side, and the patients take one envelope each in order of entering the design, and according to the letter in the envelope (A or B) are divided into two groups, and only the ward nurse knows that which group must receive the intervention, but the person in charge of data collection, the head of the laboratory and information analysis does not know which group received the intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahrud University of Medical Sciences

Street address

Shahrud University of Medical Sciences, 7 Tir Square, Shahrud

City

Shahrud

Province

Semnan

Postal code

36147-73947

Approval date

2020-04-04, 1399/01/16

Ethics committee reference number

IR.SHMU.REC.1399.013

Health conditions studied**1****Description of health condition studied**

COVD-19 patient

ICD-10 code

U07.1

ICD-10 code description

covid-19, virus identified

Primary outcomes**1****Description**

Clinical course

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

By recording information about the variables defined from the patients' hospital records

2**Description**

Paraclinical

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Registration of patient's laboratory information and CT scan

3**Description**

outcome

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Doctor's approval and death certificate

Secondary outcomes**1****Description**

Duration of hospitalization

Timepoint

End of hospitalization

Method of measurement

Hospital file

2**Description**

Severe chest pain

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Ask the patient

3**Description**

Severe shortness of breath

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Ask the patient

4**Description**

how many days after hospitalization they died

Timepoint

End of hospitalization

Method of measurement

ask the patient

Intervention groups**1****Description**

Intervention group: Intramuscular Injection of 300 milligrams of vitamin D at the beginning of the week, as well as another dose at the beginning of the week.

Category

Treatment - Other

2**Description**

Control group: This group are treated by normal treatment process without any intervention

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hossein Shahroud Hospital

Full name of responsible person

hossien sheybani

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Shahroud University of Medical Sciences, 7 Tir Square, Shahroud

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

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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

Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Erfan Kazemi
Position
student
Latest degree
A Level or less
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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
All data is made available to the public after unidentifiable identification
When the data will become available and for how long
Data access period begins 2 months after the article is published
To whom data/document is available
It will be available only to researchers working in

academic and scientific institutions or to people working in the industry

Under which criteria data/document could be used

They can do any kind of analysis with data. And the data can be used in any research direction, otherwise it must be coordinated with the researcher.

From where data/document is obtainable

email:erfankazemi305@gmail.com number:0098 9155868605

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

Applicants can contact us by e-mail or the mentioned number to receive information.

Comments