

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effect of high dose of vitamin D on mortality, length of stay and inflammatory markers on Covid 19 patients admitted in the intensive care unit

Protocol summary

Study aim

Effect of high dose of vitamin D on mortality, length of stay and inflammatory markers on Covid 19 patients admitted in the intensive care unit

Design

A parallel, double-blind, placebo controlled, randomized clinical trial

Settings and conduct

This study will be done on 60 corona virus patients who admitted in intensive care unit at Golestan hospital. Participants will be divided two groups: Ampule vitamin D and placebo

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 years and older patients, Willingness to cooperate, definitely diagnosis corona disease with positive RT-PCR and chest CT-Scan, level of vitamin D less than 30ng/dlit Exclusion criteria: Reluctance to continue cooperation, pregnant, breastfeeding, hospitalized less than 24 hour in intensive care unit, consumption omega3, vitamin A and D supplements during last month, hypoparathyroidism, hypercalcemia, sensitive to vitamin D, kinds of cancers, radiotherapy, chemotherapy, or immunotherapy, renal diseases, liver failure, patients who are

Intervention groups

Receiving 300,000 unit vitamin D ampule group and placebo group

Main outcome variables

Recovery process will be checked by SOFA and APACHE2 questionnaires. Also AST,ALT,ALKPH, CRP, ESR, WBC, FBS, IL-6, Vitamin D will be checked.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170827035936N2**

Registration date: **2021-12-19, 1400/09/28**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-19, 1400/09/28**

Update count: **0**

Registration date

2021-12-19, 1400/09/28

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3826 2052

Email address

zohreh.javadfar@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-12, 1400/08/21

Expected recruitment end date

2022-02-10, 1400/11/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of high dose of vitamin D on mortality, length of stay and inflammatory markers on Covid 19 patients admitted in the intensive care unit

Public title

Effect of vitamin D on Corona disease

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
18 years and older patients, Willingness to cooperate, definitely diagnosis corona disease with positive RT-PCR and chest CT-Scan, level of vitamin D less than 30ng/dlit
Exclusion criteria:
18 years and older patients, Willingness to cooperate, definitely diagnosis corona disease with positive RT-PCR and chest CT-Scan, level of vitamin D less than 30ng/dlit

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, both of researcher and patients do not aware about allocating groups. For this purpose, the information gathered in the questionnaires is encoded by people other than the researcher or other key collaborators, so that the researcher and the participants in the plan do not encode and enter the computer during the categorization and placement of each individual in the intervention or control group.

Placebo
Used

Assignment
Parallel

Other design features
In this study both of patients and researcher are blind about kind of investigation (vitamin D or placebo) groups

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Deputy of Research of Kermanshah University of Medical Sciences

Street address

Shahid Beheshti St., Oil Field, Facing Taleghani

Hospital, Building No. 2 of Kermanshah University of Medical Sciences, Research and Research Branch

City
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Province
Kermanshah

Postal code
6719851351

Approval date
2021-11-07, 1400/08/16

Ethics committee reference number
IRKUMS MED.REC.1400.069

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

The proportion of mortality and the period of staying in intensive care unit

Timepoint

The beginning of study until discharging from intensive care unit

Method of measurement

(Acute Physiology And Chronic Health Evaluation II Score (APACHE II and (Sequential Organ Failure Assessment score (SOFA score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of 300000 IU of vitamin D3, the beginning of study

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital in Imam Reza complex hospital

Full name of responsible person

Dr Shahram Bidhendi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Reza Khodarahmi
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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

Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person

Zohreh Javadfar
Position
Master of nutrition sciences
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

there are not more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available