Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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 controled, 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, hypoparathiroidism, 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

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kermanshah

Province

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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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Vice– Chancellery of Research & Technology Affairs, Building No. 2 of Kermanshah University of Medical Sciences, Naft Square, Shahid Beheshti blvd
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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
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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