Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the status of vitamin D and its complementary effect on the prognosis of patients with COVID-19 bedridden in Hospital

Protocol summary

Study aim
Determination the status of vitamin D and its complementary effect on the prognosis of patients with COVID-19 bedridden in Hazrat Fatemeh's Hospital

Design
The clinical trial with a control group will be performed on 120 patients with parallel, double-blind, non-randomized, phase 3 groups.

Settings and conduct
The study will be performed on patients with Covid-19 hospitalized inHazrat Fatemeh's Hospital in Kerman, which are divided into 3 groups: mild, severe and very severe based on the severity of Covid disease. At the beginning and before the intervention, a blood sample is taken to determine the level of 25 hydroxyvitamin D3, then vitamin D or placebo is injected based on the mentioned level. Participants, lead researcher, Treatment staff, Data collector, data analyzer will not know the level of the disease and the type of drug injected.

Participants/Inclusion and exclusion criteria
Being aged 20-70 years, Hospitalization, Positive polymerase chain reaction test (RT-PCR), No pre-existing already respiratory illnesses, No known chronic diseases, Not being hospitalized in the past month, Do not have stressors in a recent month, Not pregnant, Do not take certain medications or Injectable vitamin D, Lack of seasonal sensitivity؛ No entry conditions: Dissatisfaction or obedience to the treatment to continue participating in the study, Diagnosis of chronic diseases at the time of hospitalization

Intervention groups
Based on serum vitamin D level and the level and severity of Covid disease, samples are divided into 3 intervention groups and 3 control groups.

Main outcome variables
Severity of respiratory and gastrointestinal symptoms; Duration of hospitalization; Number of deaths

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210327050775N1**
Registration date: **2021-05-25, 1400/03/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-25, 1400/03/04**
Update count: **0**

Registration date
2021-05-25, 1400/03/04

Registrant information

Name
Somayeh Nikkhah

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3243 8239

Email address
nikkhah_somayeh@iauk.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2021-10-23, 1400/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the status of vitamin D and its complementary effect on the prognosis of patients with COVID-19 bedridden in Hospital

Public title
Effect of vitamin D on the prognosis of patients with COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being aged 20-70 years Hospitalization Positive polymerase chain reaction test (RT-PCR) No pre-existing already pneumonia, Chronic obstructive pulmonary diseas(COPD) and other respiratory illnesses No known chronic diseases (diabetes, hypertension, underlying heart disease, infectious, liver, kidney and epilepsy, neuromuscular, immune deficiency diseases and cancer) Not being hospitalized in the past month Do not have stressors such as the death of first-degree relatives, etc. in a recent month Not pregnant Do not use oral contraceptives, vitamin products, calcium, anticonvulsants, estrogen and diuretics Do not take injectable vitamin D in the last 6 months Lack of seasonal sensitivity
Exclusion criteria:
Dissatisfaction or obedience to the treatment to continue participating in the study Diagnosis of chronic diseases at the time of hospitalization
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, lead researcher, Treatment staff (Physicians, Nurses), Data collector, Outcome assessor and data analyzer will not know the level of the disease and the type of drug (vitamin D or placebo) and the amount of vitamin D injected. In the end of the research will be communicated to the participants.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad Tehran Medical Sciences University
Street address
No. 23, Abnoos 7., Abnoos 7 Ave
City
Kerman
Province
Kerman
Postal code
7619658464
Approval date
2020-10-13, 1399/07/22
Ethics committee reference number
IR.IAU.PS.REC.1399.172

Health conditions studied

1

Description of health condition studied
Covid-19
ICD-10 code
U07.02
ICD-10 code description
COVID-19 Disease

Primary outcomes

1

Description
Pregnosis and severity disease in patients with Covid 19
Timepoint
Determination of prognosis and severity disease in the beginning of the study (before the intervention) and 7, 14 days after the start of vitamin D intake
Method of measurement
Guidelines issued by the National Health Commission for the diagnosis and treatment of coronavirus

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients with Mild level of Covid-19 with vitamin D deficiency (less than 30 ng /ml). Intervention by taking routine medications in addition

Consumption of vitamin D in the form of calciferol 300,000 units. Number of uses: Once and at the time of hospitalization of the patient, How to use: Injection into the gluteus muscle, Manufacturer: Tehran Daroo Company.

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients with Severe level of Covid-19 with vitamin D deficiency (less than 30 ng /ml). Intervention by taking routine medications in addition Consumption of vitamin D in the form of calciferol 300,000 units. Number of uses: Once and at the time of hospitalization of the patient, How to use: Injection into the gluteus muscle, Manufacturer: Tehran Daroo Company.

Category

Treatment - Drugs

3

Description

Intervention group 3: Patients with Very severe level of Covid-19 with vitamin D deficiency (less than 30 ng /ml). Intervention by taking routine medications in addition Consumption of vitamin D in the form of calciferol 300,000 units. Number of uses: Once and at the time of hospitalization of the patient, How to use: Injection into the gluteus muscle, Manufacturer: Tehran Daroo Company.

Category

Treatment - Drugs

4

Description

Control group 1: Patients with mild level of Covid-19 with vitamin D deficiency (more than 30 ng/ml). Intervention by taking routine medications in addition Consumption of placebo(Distilled water). Number of uses: Once and at the time of hospitalization of the patient, How to use: Injection into the gluteus muscle.

Category

Treatment - Drugs

5

Description

Control group 2: Patients with severe level of Covid-19 with vitamin D deficiency (more than 30 ng/ml). Intervention by taking routine medications in addition Consumption of placebo(Distilled water). Number of uses: Once and at the time of hospitalization of the patient, How to use: Injection into the gluteus muscle.

Category

Treatment - Drugs

6

Description

Control group: Patients with very severe level of Covid-19 with vitamin D deficiency (more than 30 ng/ml). Intervention by taking routine medications in addition Consumption of placebo(Distilled water). Number of uses: Once and at the time of hospitalization of the patient, How to use: Injection into the gluteus muscle.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Fatemeh Al-Zahra Hospital

Full name of responsible person

Somayeh Nikkhah

Street address

No. 23, Abonoos7 Ave

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Phone

+98 34 3243 8239

Email

Nikkhah_somayeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Maryam Kazemipour

Street address

Islamic Azad University Kerman., Emam Ali Blvd,

City

kerman

Province

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Postal code

7635131167

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+98 34 3321 0043

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mkazemipoor@iauk.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Somayeh Nikkhah

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Full name of responsible person

Somayeh Nikkhah

Position

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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

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

In participants' individual data: Part of the data such as information about the main outcome In the study protocol: the whole method of conducting research In the statistical analysis map: statistical tests used In the form of informed consent: Only the raw form to make the participants unrecognizable

When the data will become available and for how long

Access period starts 3 months after the results are published

To whom data/document is available

Researchers working in academic, scientific and private institutions

Under which criteria data/document could be used

Research use in similar cases by providing research approval code from university centers

From where data/document is obtainable

By E-mail to the address: Nikkhah_somayeh@yahoo.com With Somayeh Nikkhah

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

After receiving the request email and also submitting the research approval code, the documents will be emailed within a week.

Comments