

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Evaluation of the Effect of Vitamin D Supplementation on the Recovery of Hospitalization Children Suffering from Coronavirus Disease 2019 in Hospital

Protocol summary

Study aim

Determination of vitamin D supplementation effect on the recovery of hospitalized children suffering from Coronavirus disease 2019

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 40 patients. Sealed Envelope online software was used for randomization.

Settings and conduct

Children 3 months to 14 years old suffering from Coronavirus disease 2019 admitted to 17 Shahrivar Hospital in Rasht city during 2021 are selected by random sampling method. Patients are randomly divided into two groups by the random block method. An online address (www.sealedenvelope.com) is used to generate a random list. Study groups include intervention group 1: receiving vitamin D at a dose of 1000 IU daily, control group: receiving placebo. To blind the type of intervention, closed and numbered envelopes are used and patients are identified with the same code until the end of the study. The doctor, the evaluator and the patient are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children suffering from Coronavirus disease 2019, 3 to 14 months old hospitalization children in hospital; Exclusion criteria: Children that have a history of hepatitis disease, children that have malabsorption disorder, children that are undergoing chemotherapy

Intervention groups

The intervention group is hospitalized children suffering from Coronavirus disease 2019 who will receive daily vitamin D with a dose of 1000 international units. The control group is hospitalized children suffering from Coronavirus disease 2019 who will receive a placebo made by Barij Essan company, daily.

Main outcome variables

Time to stop fever, stop respiratory distress and hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090909002438N4**

Registration date: **2022-10-11, 1401/07/19**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-11, 1401/07/19**

Update count: **0**

Registration date

2022-10-11, 1401/07/19

Registrant information

Name

Houman Hashemian

Name of organization / entity

Guilan University of medical sciences- Medical faculty- 17 Shahrivar hospital

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 9061

Email address

hashemian@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Effect of Vitamin D Supplementation on the Recovery of Hospitalization Children Suffering from Coronavirus Disease 2019 in Hospital

Public title
"Evaluation of the Effect of Vitamin D Supplementation on the Recovery of Children Suffering from Coronavirus Disease 2019"

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Children suffering from coronavirus disease 2019 (COVID-19) 3 months to 14 years old hospitalization children in hospital
Exclusion criteria:
Children that have a history of hepatitis disease Children that have malabsorption disorder Children that are undergoing chemotherapy

Age
From **3 months** old to **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **20**
According to the number of cases suffering from Coronavirus disease 2019 in the hospital last year (51 cases) and due to the low prevalence and vaccination of patients in recent years, 20 people in each group are selected. Samples include hospitalized children suffering from Coronavirus disease 2019 in hospitals that have 3 months to 14 years of age.

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is random block allocation, and patients will be randomly divided into two groups, including intervention with vitamin D and the control group with placebo. The randomization unit is individual and people will be selected individually. Randomization will be done in the form of sealed opaque envelopes with a random sequence. At first, each of the randomly generated sequences is recorded on a card. Then, the cards are placed in the envelopes in order. In order to maintain the random sequence, the outer surface of the numbered envelopes is placed in the same order. After that, the lid of the envelopes is glued and they are

placed in the box in order. The randomization tool is online software (www.sealed envelope.com). First, registration is done on the site. The number of blocks is 5 and 8 people are selected in each block. According to the required sample size and block size, a randomization list of people to be placed in treatment groups is produced. At the time of registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drug concealment was also performed using opaque envelopes sealed in random sequence, opaque envelopes, sealed, numbered respectively. Each random sequence created is recorded on a card and the cards are placed in the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, according to the order of entry of the participants, one of the envelopes of the letter is opened in order and the assigned group of that participant is revealed. The coding is done by one of the project partners and the evaluating physician and the patient are blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Parastar Ave., Farhang Square., Rasht Town, Iran

City

Rasht

Province

Guilan

Postal code

41937-13111

Approval date

2022-06-01, 1401/03/11

Ethics committee reference number

IR.GUMS.REC.1401.116

Health conditions studied

1

Description of health condition studied

Coronavirus Disease 2019

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

The effect of vitamin D consumption on the fever

Timepoint

Assess the severity of the Coronavirus disease 2019 at the beginning of the study (before the intervention) and every 24 hours after starting consumption of vitamin D as daily

Method of measurement

Mercury thermometer device

2

Description

The effect of vitamin D consumption on the respiratory distress

Timepoint

Assess the severity of the Coronavirus disease 2019 at the beginning of the study (before the intervention) and every 24 hours after starting consumption of vitamin D as daily

Method of measurement

Pulse oximeter device

3

Description

The effect of vitamin D consumption on hospitalization

Timepoint

Assess the severity of the Coronavirus disease 2019 at the beginning of the study (before the intervention) and every 24 hours after starting consumption of vitamin D as daily

Method of measurement

Number of days of hospitalization for treatment

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Hospitalized children with COVID-19 are 3 months to 14 years old and will receive daily vitamin D with a dose of 1000 international units

Category

Treatment - Other

2

Description

Control group: Hospitalized children with COVID-19 are 3 months to 14 years old and will receive a daily Placebo made by Barij Essence Company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

17 Shahrivar Hospital

Full name of responsible person

Houman Hashemian

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Parastar Ave., Farhang Square., Rasht Town, Iran

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hashemian@gums.ac.ir

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Houman Hashemian

Street address

Parastar Ave., Farhang Square., Rasht Town, Iran

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Grant name

Grant code / Reference number

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

No

Title of funding source

Guilan 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

Parastar Ave., Farhang Square., Rasht Town, Iran

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Rasht

Province

Guilan

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Web page address

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Person responsible for general inquiries**Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Houman Hashemian

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data**Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Houman Hashemian

Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Houman Hashemian

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address**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

Yes - There is 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 documents or patient data files will be provided to the Vice Chancellor for Research and Treatment. The results of the study will be published in the form of an article resulting from the project without mentioning the names of the participants.

When the data will become available and for how long

The access period is 6 months after the publication of results in the form of an article.

To whom data/document is available

The results of the research will be available to all researchers as a published article.

Under which criteria data/document could be used

Researchers will send a written request to executor of the project stating the reasons and details for accessing

the data and documentation. After review by the ethics committee and the research council, if approved, will be sent.

From where data/document is obtainable

Researchers will send a written request to executor of the project stating the reasons and details for accessing the data and documentation.

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

Researchers will send a written request to executor of the project stating the reasons and details for accessing the data and documentation. After review by the ethics committee and the research council, if approved, will be sent.

Comments

The applicant must also state in full detail the reason for his / her need for data and documentation.