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 cunsumtion 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
Street address
Parastar Ave., Farhang Square., Rasht Town, Iran
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Web page address
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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
City
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Web page address
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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

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 scientific inquiries

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Houman Hashemian
Position
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Specialist
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Person responsible for updating data

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Latest degree
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Web page address
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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
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.