

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of the effect of ultra-dose of vitamin D₃ as 10000 IU/Kg on clinical and laboratory results of critical children admitted to PICU

Protocol summary

Study aim

Investigating the effect of an ultra dose of vitamin D₃ in the amount of 10000 IU/Kg orally and comparing it with the usual dose of vitamin D₃ in the amount of 2000 IU orally daily on clinical and laboratory outcomes in critical children hospitalized in PICU.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 237 patients. To randomize from the table of random numbers using www.randomization.com

Settings and conduct

The study was conducted in Akbar Children's Hospital of Mashhad. The patient and the attending physician remained unaware of the method of randomization and placement of the patient in the assigned treatment group. 92 children without vitamin D deficiency (group-A) and 98 children with insufficient/low vitamin D (group-B) were examined. One group of B-group children were treated with normal dose (B1-group) and the other group with ultradose (B2-group) of vitamin D₃. Then the groups were examined in terms of laboratory factors on the first and seventh days and clinical outcomes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Critically ill children admitted to the pediatric intensive care unit healthy children Exclusion criteria: History of kidney failure History of liver diseases sepsis AIDS disease Hemodynamic instability Lack of enteral feeding Patients with hypercalcemia Patients with intestinal malabsorption Cystic fibrosis patients

Intervention groups

One group ultra dose of vitamin D₃ in the amount of 100,000 oral units and in the group of vitamin D₃ with a standard dose (400 units)

Main outcome variables

vitamin D; Calcium; phosphorus; PTH; alkaline phosphatase; AST; ALT; non-fasting blood sugar; urea; Creatinine; albumin; hemoglobin; WBC; percentage of neutrophils and lymphocytes; NLR; CRP; GFR; Urinary

calcium and creatinine.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221129056657N1**

Registration date: **2023-01-17, 1401/10/27**

Registration timing: **retrospective**

Last update: **2023-01-17, 1401/10/27**

Update count: **0**

Registration date

2023-01-17, 1401/10/27

Registrant information

Name

Gholamreza khademi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3189 1780

Email address

khademigh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

2019-04-21, 1398/02/01

Actual recruitment end date

2020-04-20, 1399/02/01

Trial completion date

2020-04-20, 1399/02/01

Scientific title

Evaluation of the effect of ultra-dose of vitamin D₃ as 10000 IU/Kg on clinical and laboratory results of critical children admitted to PICU

Public title

The effect of ultra-dose of vitamin D₃ on critical children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of one month to 18 years Healthy children Critically ill children admitted to the PICU Healthy children

Exclusion criteria:

Chronic kidney disease and nephritic syndrome Severe parenchymal or obstructive liver disease Vitamin D-dependent rickets type B1 (VDDR-1B) and type A1 (VDDR-1A) Hereditary vitamin D resistant rickets (HVDRR) High-dose glucocorticoid treatment AIDS treated with antiretroviral drugs Patients treated with phenytoin, phenobarbital, carbamazepine, isoniazid, theophylline and high doses of glucocorticoid Lack of oral or enteral nutrition Patients with hypercalcemia, intestinal malabsorption such as celiac disease and IBD, exocrine pancreatic disorder such as cystic fibrosis History of bowel resection or bariatric surgery Suffering from a chronic disease or current severe disease (in outpatients)

Age

From **1 month** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **138**

Actual sample size reached: **237**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual simple randomization Random number table randomization tool using www.randomization.com Allocation Concealment method: envelopes closed In this method, first, a random sequence is created, then based on the size of the research sample, a number of envelopes with aluminum wrappers (in order to avoid the clarity of the contents of the envelopes), are prepared and each of the generated random sequences is recorded on a card, and the cards are inside The letter envelopes are placed in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of participants, based on the order in which eligible participants entered 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

In order to perform blinding, ICU nurses, ICU doctors, the patient's treating physician, laboratory experts, statistical consultant,s and data analysts remained unaware of the method of randomization and placement of the patient in the assigned treatment group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Akbar hospital, Kaveh Blvd., Mashhad Town

City

Mashhad

Province

Razavi Khorasan

Postal code

9177897157

Approval date

2019-04-17, 1398/01/28

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.761

Health conditions studied

1

Description of health condition studied

Vitamin D deficiency in critically ill children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

C-reactive protein factor

Timepoint

on the first day of the study and the seventh day after the intervention

Method of measurement

Taking blood samples and laboratory kits

2

Description

Length of hospitalization in the intensive care unit

Timepoint

On the seventh day after the intervention

Method of measurement

Refer to the patient file

Secondary outcomes

1

Description

Percentage of possible mortality

Timepoint

First day of study

Method of measurement

Completing the Prism form

2

Description

Duration of hospitalization

Timepoint

The seventh day after the start of the intervention

Method of measurement

Complete the checklist

3

Description

Duration of intubation

Timepoint

The seventh day after the start of the intervention

Method of measurement

Complete the checklist

4

Description

Vitamin D levels

Timepoint

The first day of the study and the seventh day after the start of the intervention

Method of measurement

Using the ELISA laboratory kit (Enzyme-linked immuno_sorbent assay)

Intervention groups

1

Description

The usual dose of vitamin D₃ is 2000 IU orally (gavage), once a day, for 7 days - manufactured by Zahrawi Pharmaceutical Company, Tabriz

Category

Treatment - Drugs

2

Description

Ultra dose of vitamin D₃ in the amount of 10000 IU/Kg orally (gavage) (maximum IU 400000), once a day, for 7 days, manufactured by Zahrawi Pharmaceutical Company, Tabriz

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Children's Hospital

Full name of responsible person

Gholamreza Khademi

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Akbar Children's Hospital, Shahid Kaveh Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayor Mobarhan

Street address

3rd floor, University Research and Technology Vice-Chancellor, University of Medical Sciences, University Street, Mashhad

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Grant name

Grant from Mashhad University of Medical Sciences

Grant code / Reference number

IR.MUMS.MEDICAL.REC.1397.761

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

Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Gholamreza Khademi
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

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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

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

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

Part of the data related to the main outcomes

When the data will become available and for how long

Six months after the results are published

To whom data/document is available

Academic institutions

Under which criteria data/document could be used

For the purpose of research for the academic community

From where data/document is obtainable

With Dr. Gholamreza Khademi, co-response author
khademigh@mums.ac.ir

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

Request via email to Dr. Gholamreza Khademi After the correspondence, the data will be sent about two weeks after the registration of the request.

Comments