Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Correlation between high dose of vitamin D3 and rise of hemoglobin in mechanical ventilation patients in medical ICU

Protocol summary

Study aim
Evaluation of correlation between high dose vitamin D3 prescription and rise of hemoglobin

Design
A clinical trial with two groups of intravenous Vitamin D and control, with parallel groups, randomized based on simple randomization with https://www.randomizer.org site,double-blind phase 3 with 50patients in each group (totally 100)

Settings and conduct
in this double-blind randomized clinical trial nurse will give the patient vitamin A3 or placebo. For this purpose, during 6 months in Imam Hossein Hospital, ICU Medical ward, all patients admitted who have the conditions to enter the study and are under mechanical ventilation are randomly divided into two groups. After recording the demographic information, including age, sex, and underlying diseases, the objectives of the study will be explained to the patient and they will enter the study if they wish and obtain written consent. First, the concentration of hemoglobin and the level of vitamin D3 are checked. Then, in a placebo group and in a group of vitamin D3 with 50,000 units, we gavage for 5 days. We record the patient's hemoglobin level one week later. Hemoglobin will be measured and recorded once a week for a maximum of one month.

Participants/Inclusion and exclusion criteria
100 patients over 18 years of age, under mechanical ventilation, admitted to the internal ICU, who are hospitalized in the ICU for 6 months and undergo mechanical ventilation, will be randomly assigned to the two treatment groups with vitamin D and placebo. Patients with chronic liver and kidney disease anemia and patients discharged from the ECU 12 days ago are excluded from the study.

Intervention groups
Intervention group (Vitamin D): Nurse for this group Vitamin D3 with 50,000 units for 5 days of gavage Control group: The ward nurse injects a placebo for the opposite group

Main outcome variables
Measure and record hemoglobin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200612047743N1**
Registration date: **2021-06-22, 1400/04/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-22, 1400/04/01**
Update count: **0**

Registration date
2021-06-22, 1400/04/01

Registrant information

Name
Amin Sahranavardshirazi

Name of organization / entity

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Iran (Islamic Republic of)

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aminm5571@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2022-02-20, 1400/12/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Correlation between high dose of vitamin D3 and rise of hemoglobin in mechanical ventilation patients in medical ICU

Public title

Effect of vitamin D3 in rise of hemoglobin

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

patients under mechanical ventilation in ICU Non surgical patients

Exclusion criteria:

Non mechanical ventilated patients anemia Chronic kidney and liver disease Abnormal deficiency and increase of vitamin D3 Patients discharged from the ICU before 12 days

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization - Randomization unit: individual -Randomization tool: Randomization will be done using the site https://www.randomizer.org which using random numbers extracted by the software, patients will be given one of the two groups of Vitamin D and control. Input software: number of sets (in our study a set of 100) Number of samples in each set (100 samples in total) The range of data in each set (in our study from 1 to 2, ie 1 group therapy and 2 placebo groups, separation from 50 to 1 50 to 2) Output software: one set of 100 numbers from 1 to 2 that are placed in the treatment group or placebo at the time of infection using these 1 and 2 drug codes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drugs for both groups will be prepared and coded by one of the researchers in the study. Participants in the study who enter the study after obtaining informed consent. In this study, the first group of patients was given oral vitamin D and the second group was given a placebo. The patients' blood samples were taken and their hemoglobin was checked by ICU doctors, who did not know which vitamin D disease or which placebo they were taking.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshtee University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Shahid Erabi St, Ebne Yaman St, Shahid Chamran Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-05-21, 1398/02/31

Ethics committee reference number

IR.SBMU.MSP.REC.1398.212

Health conditions studied

1

Description of health condition studied

Vitamin D deficiency to prevent anemia in patients undergoing mechanical ventilation

ICD-10 code

R82.3

ICD-10 code description

Primary outcomes

1

Description

Patient hemoglobin level

Timepoint

First, study the hemoglobin concentration and vitamin D3 levels. The patient's hemoglobin level is then recorded one week after the intervention. Hemoglobin will be measured and recorded once a week for a maximum of one month.

Method of measurement

Flow measures the hemoglobin level by a blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The treatment method in this study is vitamin D injection (a fat-soluble supplement that is effective in absorbing calcium, phosphate and magnesium in the intestine. It is effective in strengthening bones and teeth by balancing calcium and phosphorus in the body and reducing their renal excretion). At a dose of 50,000 units for 5 days of gavage. One of the several benefits of vitamin D is the treatment or improvement of anemia, which in this study, with the aim of increasing the patient's hemoglobin, patients receive vitamin D.
Category
Prevention

2

Description
Control group: Placebo
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
amin sahranavard shirazi
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Sponsors / Funding sources

1

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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
Shahid Beheshti 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable