

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 50 patients in each group (totally 100)

Settings and conduct

In this double-blind randomized clinical trial, the nurse will give the patient vitamin D3 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 ICU 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

Country

Iran (Islamic Republic of)

Phone

+98 21 2246 2466

Email address

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

Street address

Imam Hossein Hospital, Shahid Madani St, Tehran

City

tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7756 7840

Email

aminm5571@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

afshin zarghi

Street address

University Blvd, Velenjak

City

tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 2243 9781

Email

aminm5571@yahoo.com

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

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

sara salarian

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Hossein Hospital, Shahid Madani St

City

tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7756 7840

Email

sarasalarian@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sara Salarian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Hossein Hospital, Shahid Madani St

City

tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7756 7840

Email

sarasalarian@yahoo.com

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sara Salarian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Hossein Hospital, Shahid Madani St

City

tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7756 7840

Email

sarasalarian@yahoo.com

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