

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparison of the efficacy of high and low doses vitamin D supplementation on serum levels of inflammatory factors and mortality in patients with severe head trauma.

#### Protocol summary

##### Study aim

Comparison of the effect of high and low doses of vitamin D supplementation on serum levels of inflammatory factors and mortality rate in patients with severe head trauma

##### Design

Two arm parallel group double blind randomized clinical trial with post-trauma care and outcome assessment

##### Settings and conduct

The VITdAL-ICU study is a randomized, double-blind, placebo-controlled trial investigating the effects of a daily dose of 100000 IU vitamin D3 versus 1000 IU vitamin D3 for 5 days on inflammatory makers and mortality rate (primary outcomes) in severe traumatic brain injury adults. Participants (N = 70, age 18-65 years) were recruited from the neurocritical care unit from Kamyab and Taleqani hospitals. Eligibility criteria included the presence of traumatic brain injury, Glasgow coma scale between 7 -9 and serum 25-hydroxyvitamin D levels lower than 20 nmol/L. Patients are randomly assigned to intervention group (A) and control (B) and receive daily coded vitamin D drops.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Head trauma, Glasgow coma scale (GCS) between 7 to 9, vitamin D level less than 20 nmol / g. Exclusion criteria: receive corticosteroid, total parenteral nutrition, age above 65 years old

##### Intervention groups

In the intervention group, vitamin D, 100,000 IU per day is given. In the control group vitamin D, 1000 IU per day is prescribed by gavage.

##### Main outcome variables

Mortality, Interleukin- 6 (IL-1), C-Reactive Protein (CRP) , Monocyte chemoattractant protein-1 (MCP-1)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180619040151N3**

Registration date: **2019-08-10, 1398/05/19**

Registration timing: **prospective**

Last update: **2019-10-06, 1398/07/14**

Update count: **1**

##### Registration date

2019-08-10, 1398/05/19

##### Registrant information

##### Name

Abdolreza Norouzy

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3800 2382

##### Email address

norouzya@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-11, 1398/05/20

##### Expected recruitment end date

2019-12-21, 1398/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the efficacy of high and low doses vitamin D supplementation on serum levels of inflammatory factors and mortality in patients with severe head trauma.

## Public title

Effect of vitamin D in severe traumatic brain injury

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having vitamin D levels below 20 nmol/g/ml at the time of admission in the ICU Glasgow coma scale (GCS) Between 7 and 9 Completion of informed consent form from patients' first-degree relatives Achieving hemodynamic stability (no arterial pressure lower than 60 mmHg for at least 3 hours, stopping development epidural, subdural or intracranial hematoma) Enteral ability to feed in the first 24 to 48 hours of admission Receiving the standard dose of Dilantin according to the treatment protocol for patients with traumatic brain injury Age 18 to 65 years

### Exclusion criteria:

Receiving Corticosteroids Severe and active bleeding Receive hydrochlorothiazide, digoxin and magnesium-containing antioxidants History of treatment with a high dose of 1000 units of vitamin D in the last 4 months Sepsis and pneumonia at the beginning of the study Hyperparathyroidism, sarcoidosis, nephrolithiasis, chronic renal failure, cirrhosis and AIDS Presence of autoimmune disease Hypercalcemia at the beginning of the study (calcium-albumin more than 10.8) Cancer, diabetes, and cardiovascular disease Pregnancy

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

For randomization, the permuted block randomization method with blocks of size 4 is used. According to the sample size of 80, 20 blocks of size four will be produced using the online site ([www.sealedenvelope.com](http://www.sealedenvelope.com)).

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In order to apply blur in the randomization process, unique codes will be used on supplemental boxes, which will be generated by this software. By entering each

individual into a study based on the sequence produced, the boxes of the drug that the code is registered on is assigned to the person and therefore, before the person is selected, one does not know the type of treatment he receives. Given that the box of vitamin D and placebo are named by the codes, the investigator, the patient, and the data analyzer are blinded.

## Placebo

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

Azadi square

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948564

#### Approval date

2018-10-06, 1397/07/14

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.381

## Health conditions studied

### 1

#### Description of health condition studied

Epidural hemorrhage

#### ICD-10 code

S06.4

#### ICD-10 code description

Epidural hemorrhage

### 2

#### Description of health condition studied

Traumatic subdural hemorrhage

#### ICD-10 code

S06.5

#### ICD-10 code description

Traumatic subdural hemorrhage

## Primary outcomes

## 1

### **Description**

Interleukin-6

### **Timepoint**

Measurement of Interleukin-6 at the beginning of the study and on days 7 and 14 after vitamin D supplementation

### **Method of measurement**

Serum measurement with ELISA method

## 2

### **Description**

Monocyte Chemoattractant Protein-1 (MCP-1)

### **Timepoint**

Measurement of Monocyte Chemoattractant Protein-1 at the beginning of the study and on days 7 and 14 after vitamin D supplementation

### **Method of measurement**

Serum measurement with ELISA method

## 3

### **Description**

C-reactive protein

### **Timepoint**

Measurement of C-reactive protein at the beginning of the study and on days 7 and 14 after vitamin D supplementation

### **Method of measurement**

Serum measurement with ELISA method

## 4

### **Description**

28 days mortality

### **Timepoint**

Measurement of mortality at the beginning of the study and day 28

### **Method of measurement**

Death record

## **Secondary outcomes**

## 1

### **Description**

Delirium

### **Timepoint**

Before intervention, day 7 and 14

### **Method of measurement**

The Confusion Assessment Method for the ICU

## 2

### **Description**

Glasgow coma score

### **Timepoint**

Before intervention, day 7 and 14

### **Method of measurement**

Glasgow Coma Scale

## 3

### **Description**

Acute Physiology and Chronic Health Evaluation (APACHE II) score

### **Timepoint**

Before intervention, day 7 and 14

### **Method of measurement**

Acute Physiology and Chronic Health Evaluation (APACHE II) score

## 4

### **Description**

Sequential Organ Failure Assessment (SOFA) score

### **Timepoint**

Before intervention, day 7 and 14

### **Method of measurement**

Sequential Organ Failure Assessment (SOFA) Score

## **Intervention groups**

## 1

### **Description**

Intervention group: drop of vitamin D3, 100000 IU daily for 5 days, and 1000 IU daily from day 6 to day 14

### **Category**

Treatment - Drugs

## 2

### **Description**

Control group: drop of vitamin d3 1000 IU, daily for 14 days

### **Category**

Placebo

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Shahid Kamyab hospital

#### **Full name of responsible person**

Abdolreza Norouzy

#### **Street address**

Fadaian Eslam street

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

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#### **Phone**

+98 51 3882 7033

#### **Email**

norouzya97@gmail.com

## 2

### **Recruitment center**

**Name of recruitment center**

Shahid Kamyab hospital

**Full name of responsible person**

Abdolreza Norouzy

**Street address**

North Azadi Ave

**City**

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**Province**

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**Email**

norouzya97@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**Mashhad University of Medical Sciences, Daneshgah  
18 Avenue, Daneshgah street**City**

Mashhad

**Province**

South Khorasan

**Postal code**

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**Phone**

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**Fax**

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**Email**

tafaghodim@mums.ac.ir

**Web page address****Grant name****Grant code / Reference number****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**

Seyed Mostafa Arabi

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

Azadi square

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

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**Full name of responsible person**

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**Email**

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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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available