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 reletives Achieving hemodynamic stability (no arterial pressure lower than 60 mmHg for at least 3 hours, stopping development epidoral, subdural or interacranial hematoma) Entreal 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).

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
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Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

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Name of organization / entity
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Full name of responsible person
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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
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Person responsible for updating data

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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