

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 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)

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+98 51 3800 2382

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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).

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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Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****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****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

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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