Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Investigating the effect of neuroprotective vitamin D on Traumatic Brain injury patients

Protocol summary

Study aim
The effect of neuroprotective vitamin D in brain trauma patients in Imam Khomeini hospital in Sari
Design
A randomized, controlled, A blind strain, placebo-controlled clinical trial
Settings and conduct
The Neurosurgery Department of Imam Khomeini Hospital in Sari has six months to collect the samples.
Participants/Inclusion and exclusion criteria
All patients admitted to the emergency department and then transferred to the neurosurgery ward or the ICU during the study period, in the census, without voluntary selection, make up the sample size. Patients with brain death, grade 3 consciousness, patients who are hospitalized for less than 5 days, penetrating cerebral trauma, severe non-cerebral lesions such as hemotorax or hemo-peritoneum, or any injuries requiring rapid surgery, and There was no opportunity for neurological examination in the early stages and vitamin D deficiency was reported based on standard amounts. And less than 30 ng and more than 60 ng / ml
Intervention groups
1. In the first group, administration of VDH is performed in a single dose (150,000 units) after admission The second group, the control group, is given placebo
Main outcome variables
level of consciousness

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191026045243N2**
Registration date: **2019-12-23, 1398/10/02**
Registration timing: **retrospective**
Last update: **2019-12-23, 1398/10/02**
Update count: **0**
Registration date
2019-12-23, 1398/10/02

Registrant information
Name
Sajad Shafiee
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-10-22, 1398/07/30
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
Investigating the effect of neuroprotective vitamin D on Traumatic Brain injury patients

Public title
A trial of neuroprotective vitamin D in traumatic brain injury patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

All patients admitted to the emergency department and then transferred to the neurosurgery ward All patients admitted to the emergency department and then transferred to the ICU ward

Exclusion criteria:

Patients with brain death Equal degree of vigilance Patients hospitalized for less than 5 days Penetrating brain injuries Accompanying severe lesions Severe lesions other than brain injuries such as hemothorax or hemo-peritoneum or any injury requiring rapid surgery and no opportunity for neurological examination in the early stages. itamin D deficiency according to the standard amount reported. And less than 30 ng and more than 60 ng / ml

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a randomized clinical trial in patients with inclusion criteria. Within 5 days of admission, the envelopes were placed in envelopes with specified numbers that were given to patients when administered by a nurse who did not know the contents of the envelopes. According to the patients in the two study groups, patients in group A received a single syringe containing 2 CC vitamin D and patients in group B received a placebo containing a single syringe containing 2 CC of distilled water. All patients will be screened for consciousness on the first day before the beginning of the split. In both groups, the status of consciousness will be re-evaluated and compared within 7 days after the last administration

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Imam Hospital of Sari, Mazandaran University of Medical Sciences

Street address

Neurosurgery Department, Imam Khomeini Hospital, Amir Mazandarani Ave.

City

Sari

Province

Mazandaran

Postal code

48166-33131

Approval date

2019-07-16, 1398/04/25

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1398.117

Health conditions studied

1

Description of health condition studied

Cerebral trauma

ICD-10 code

S06

ICD-10 code description

Intracranial injury

Primary outcomes

1

Description

Level of consciousness

Timepoint

Baseline and 7 and 90 days

Method of measurement

Glasgow level of consciousness

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All patients have vitamin D levels above 30. In the first group, daily VDH is administered for 5 days after admission and in the second group, the control group is given placebo.

Category

Treatment - Drugs

2

Description

Control group: All patients had vitamin D levels above 30 in the second group receiving placebo

Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hospital
Full name of responsible person
Sajad Shafiee
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Sari 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
Mazandaran University of Medical Sciences
Full name of responsible person
Sajad Shafiee
Position
Associate professor
Latest degree
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Web page address
https://fa.irct.ir/user/trial/43279/update/scientific_queries_contact

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
Undecided - It is not yet known if there will be 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