Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of vitamin D administration on intensive care unit patient’s with Aneurysmal SAH outcomes: A randomized controlled trial study

Protocol summary

Study aim

Due to the role of vitamin D in the immune system, cardiovascular system and brain researchers decided to investigate the effect of vitamin D on the clinical outcome of patients admitted to the neurosurgical intensive care unit with cerebral aneurysmal subarachnoid hemorrhage.

Design

Based on vitamin D levels, 68 patients were divided into two groups: patients with serum vitamin levels between 10 and 30 and patients that serum vitamin levels between 30 and 100. Again, the groups were divided into two groups control and intervention. So finally, we will have 4 groups.

Settings and conduct

This study will be performed in the neurosurgery ICU of Ghaem Hospital in Mashhad. Patients are divided into 4 groups. Our intervention in this study is vitamin D injection. And we will have two intervention groups. ŝimilar to intervention groups we will have two control groups for better and more accurate comparison. On the 3rd day after bleeding that, patients have a relatively stable condition, an injectable dose of vitamin D containing 300,000 units of vitamin D will be injected intramuscularly. This amount of vitamin D does not cause poisoning effects for those who have blood levels below 100. The results will then be evaluated during hospitalization.

Participants/Inclusion and exclusion criteria

Patients with aneurysmal SAH Patients admitted to the ICU Age over 18 years Consciousness level based GCS score between 7 and 15

Intervention groups

in the intervention group, patients receive 300,000 units of vitamin D that are injected intramuscularly at 3rd day after SAH.

Main outcome variables

Mortality rate Clinical outcome based on mRs and GOS Duration of hospitalization in the ICU

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211208053333N1**
Registration date: **2022-04-03, 1401/01/14**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-03, 1401/01/14**
Update count: **0**

Registration date

2022-04-03, 1401/01/14

Registrant information

Name

Ali Mohammad Sarbezi Roudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2613

Email address

pishjoum951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-18, 1400/12/27

Expected recruitment end date

2022-07-21, 1401/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of vitamin D administration on intensive care unit patient’s with Aneurysmal SAH outcomes: A randomized controlled trial study

Public title
The effect of vitamin D on the outcome of patients with cerebral hemorrhage hospitalized in the intensive care unit
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering Aneurysmal SAH ICU Admission Consciousness level based on GCS score between 7 to 15 Serum vitamin D levels between 10 and 100 IU
Exclusion criteria:
Pregnancy hypercalcemia (calcium greater than 10.8 mg / dl or ionized calcium greater than 5.2 mg / dl) Serum vitamin D level less than 10 Treatment with high doses of vitamin D (50,000 IU or more per week) to treat vitamin D deficiency in the last 6 months
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Building a random sequence
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients will not be informed about the type of treatment they are receiving (medication or placebo) and nurses working in the intensive care unit will not know patients groups.
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
Department of Neurosurgery , Ghaem Hospital, Ahmad Abad St, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
3133815136
Approval date
2019-09-03, 1398/06/12
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.662

Health conditions studied

1

Description of health condition studied
Aneurysmal subarachnoid hemorrhage
ICD-10 code
I60
ICD-10 code description
Nontraumatic subarachnoid hemorrhage

Primary outcomes

1

Description
Mortality rate
Timepoint
in hospitalization period
Method of measurement
Based on clinical observations

2

Description
clinical outcome
Timepoint
At discharge and 6 months later
Method of measurement
Glasgow Outcome Score and modified rankin scale

3

Description
Hospitalization period
Timepoint
at discharge
Method of measurement
Duration of hospitalization by day

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients with vitamin D level between 10 to 30 (In this group, a dose of injectable vitamin D containing 300,000 units will be injected intramuscularly at the 3rd day after admission.)
Category
Treatment - Drugs

2

Description
Intervention group: patients with serum vitamin D level between 31 to 100 (In this group, a dose of injectable vitamin D containing 300,000 units will be injected intramuscularly at 3rd day after admission.)
Category
Treatment - Drugs

3

Description
Control group: patients with serum vitamin D level between 10 to 30 (In this group, 2 cc of distilled water will be injected intramuscularly as a placebo.)
Category
Placebo

4

Description
Control group: patients with vitamin D level between 31 to 100 (In this group, 2 cc of distilled water will be injected intramuscularly as a placebo.)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Dr. Ali Mohammad Sarbazi
Street address
Ghaem hospital , Ahmadabad St
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
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+98 51 3801 2613
Email
sarbeziam951@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Ali Mohammd Sarbezi
Street address
Fakori St, Mashhad University of Medical Sciences
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938813944
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+98 51 3841 2081
Email
presidentoffice@mums.ac.ir
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
Dr.Ali Mohammad Sarbezi
Position
Resident of Neurosurgery
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
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Person responsible for scientific inquiries

Contact

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Mashhad University of Medical Sciences

Full name of responsible person
Ali Mohammad Sarbezi

Position
Resident of Neurosurgery

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Specialist

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentifing individuals

When the data will become available and for how long
1 year after publication

To whom data/document is available
Researchers working in academic and scientific institutions will be available

Under which criteria data/document could be used
for observation only

From where data/document is obtainable
email

What processes are involved for a request to access data/document
approximately one week

Comments