

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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. Similar 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

pishjourn951@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	
<u>1</u>	
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	
<u>1</u>	
Description of health condition studied	Aneurysmal subarachnoid hemorrhage
ICD-10 code	I60
ICD-10 code description	Nontraumatic subarachnoid hemorrhage
Primary outcomes	
<u>1</u>	
Description	Mortality rate
Timepoint	in hospitalization period
Method of measurement	Based on clinical observations
<u>2</u>	
Description	clinical outcome
Timepoint	At discharge and 6 months later
Method of measurement	Glasgow Outcome Score and modified rankin scale
<u>3</u>	
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

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Razavi Khorasan

Postal code

9176699199

Phone

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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 Mohammmd Sarbezi

Street address

Fakori St, Mashhad University of Medical Sciences

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938813944

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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

Street address

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Person responsible for scientific inquiries

Contact

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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 unidentifying 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