

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Investigating the effect of memantine in preventing vasospasm in SAH patients with consciousness level 9-15

Protocol summary

Study aim

Determining the effect of memantine in preventing vasospasm in SAH patients with consciousness level 9 to 15

Design

This study is a double-blind, randomized clinical trial using the variable blocks method. In this study, the limited randomization method (according to the sample size) was used to generate a random sequence using the block method and the Random allocation software.

Settings and conduct

This study will be conducted as a clinical trial in Imam Khomeini Hospital, Sari, on patients referred with the diagnosis of subarachnoid hemorrhage (SAH) with level of consciousness 9 to 15. All patients who will enter the study will undergo a diagnostic CT scan and receive the usual treatment process. Patients will be randomly assigned during the study using random numbers in two control groups (Sham) and memantine group. This study will be double blind. A diagnostic CT scan will be performed on all patients enrolled in the study and the usual treatment process will begin for both groups. Also, the level of consciousness of the patients (GCS), signs and symptoms of the disease and assessment of behavioral disorders at the time of arrival and one week later, as well as the risk of vasospasm based on the Fisher scale at the time of arrival, will be evaluated by a neurosurgeon. The patient and the person examining the CT scan results will not know the type of medicine received.

Participants/Inclusion and exclusion criteria

Patients with SAH; Patients with consciousness level 9 to 15

Intervention groups

Patients in the memantine group were treated double-blind with memantine (manufactured by Subhan company) 10 mg (2 tablets of 5 mg), twice a day, and the placebo group, treated with similar tablets in terms of appearance characteristics without the active

ingredient, twice a day for 7 days are placed

Main outcome variables

Consciousness level of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180826040869N3**

Registration date: **2023-12-12, 1402/09/21**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-12, 1402/09/21**

Update count: **0**

Registration date

2023-12-12, 1402/09/21

Registrant information

Name

Misagh Shafizad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 1700

Email address

mi.shafizad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-09, 1402/09/18

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Investigating the effect of memantine in preventing vasospasm in SAH patients with consciousness level 9-15

Public title
Investigating the effect of memantine in preventing vasospasm in SAH patients with consciousness level 9-15

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age above 18 years Visit within the first 24 hours of the onset of symptoms Confirmation of subarachnoid hemorrhage by the plan's neurosurgeon (based on history, clinical findings and CT scan or brain MRI) Patients with consciousness level 9 to 15 Consent of the patient or her legal guardian (in case of consciousness disorder) to participate in the study

Exclusion criteria:

Lack of patient consent to participate in the study Patients with a history of SAH or cerebral infarction Patients diagnosed with hydrocephalus Patients with secondary cerebral hemorrhage History of allergy to memantine Kidney failure stage 4 or 5 based on Acute Kidney Injury Network criteria (27) Moderate to severe liver disease (Child-Pugh criteria, grade B and C) (28) Having a history of epilepsy History of dementia The patient has a history of taking memantine in the last 6 months of pregnancy or breastfeeding

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
The number of 30 patients diagnosed with subarachnoid hemorrhage was selected as available and by block randomization method One of two intervention groups (15 people) and placebo (15 people) will take place. For random arrangement of samples in blocks of Random Allocation software version 2 was used. In this software, the number of groups is 2 (1: intervention and 2: placebo), the number of samples is 30, the size of the blocks is equal, and the coding is a combination of letters and numbers and random put. The statistically

significant level was also set at 0.05. Next, for random allocation from the SNOSE method was used This method is one of the common methods in hiding random allocation. In this method, the first sequence It is randomly created using the mentioned software, then based on the sample size of the study, a number of envelopes with wrappers aluminum (in order not to clarify the contents of the envelopes), preparation and each of the random sequences created (intervention group or Placebo) is recorded on a card and the cards are placed in the envelopes in order. in order to preserve The random sequence is also named on the outer surface of the envelopes in the same order as it was produced by the software take Finally, the lids of the envelopes are glued and placed in a box. At the time of registration Participants, based on the order of entry of eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants in this study were unaware of the type of drug received (memantine or placebo). For this purpose, memantine and placebo were prescribed to the patients on a daily basis with the same shape and size in both groups. Nurses who were responsible for providing medicine to patients during hospitalization were not aware of the type of medicine and the assigned group of each patient. The research associate of the project, who was responsible for collecting the signs and symptoms of the patients for the final review of the clinical results, was unaware of the assigned group of patients in order to minimize the bias in the study. Finally, the person analyzing the results of the study using coding was blinded to the type of treatment group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Organizational Research of Imam (RA) Sari Educational and Therapeutic Hospital

Street address

Imam Hospital, Amirmazandarani boulevard

City

Sari

Province

Mazandaran

Postal code

4816633131

Approval date

2019-12-25, 1398/10/04

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1398.166

Health conditions studied

1

Description of health condition studied

vasospasm

ICD-10 code

I67.848

ICD-10 code description

Other cerebrovascular vasospasm and vasoconstriction

Primary outcomes

1

Description

GCS

Timepoint

After surgery for 1 week

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

vasospasm

Timepoint

Before surgery and 1 week after surgery

Method of measurement

angiography

Intervention groups

1

Description

Intervention group: Memantine (manufactured by Subhan Co.) 10 mg (2 tablets of 5 mg), twice a day, for 7 days

Category

Treatment - Drugs

2

Description

Control group: Plasboza, according to appearance characteristics, without active ingredients, twice a day for 7 days

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam Sari Hospital

Full name of responsible person

Misagh Shafizad

Street address

Amir Mazandarani Blvd ,Sari

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3336 1700

Fax

+98 11 3336 1700

Email

mi.shafizad@gmail.com

Web page address

<https://www.mazums.ac.ir/>

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeidi

Street address

Moalem Blvd., Sari

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷-۳۳۹۷۱

Phone

+98 11 3448 4854

Fax

+98 11 3335 2725

Email

saedi@domian.com

Web page address

<https://www.mazums.ac.ir/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mazandaran 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

Misagh Shafizad

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Amir Mazandrani Blvd, Sari

City

Sari

Province

Mazandaran

Postal code

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Phone

+98 11 3336 1700

Fax

+98 11 3336 1700

Email

mi.shafizad@gmail.com

Web page address

<https://www.mazums.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Misagh Shafizad

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Amir Mazandarani Blvd ,Sari

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3336 1700

Fax

+98 11 3336 1700

Email

mi.shafizad@gmail.com

Web page address

<https://www.mazums.ac.ir/>

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Misagh Shafizad

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Amir Mazandarani Blvd ,Sari

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3336 1700

Fax

+98 11 3336 1700

Email

mi.shafizad@gmail.com

Web page address

<https://www.mazums.ac.ir/>

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