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)

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+98 11 3336 1700

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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
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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
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Fax
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Email
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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

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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