

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparison of the effect of memantine and placebo on NSE and GCS of traumatic brain injury patients: a randomized double blind, placebo controlled clinical trial

#### Protocol summary

##### Study aim

Comparison of the effect of memantine and placebo on Glasgow Coma Scale (GCS) and serum levels of NSE in traumatic brain injury (TBI) patients

##### Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, on 60 patients (30 people in intervention group and 30 people in control group). The process of block random allocation of patients will be done with random allocation software (15 blocks of size four).

##### Settings and conduct

This study is a randomized controlled trial with placebo. The target population of this study will be brain injury patients who are hospitalized in the ICU of Imam Hospital in Sari. Participants, physicians, nurses, data collection assistants, and those evaluating the outcome are unaware of the type of intervention being assigned. The appearance and packaging of the drug and placebo are similar.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: TBI; Primary GCS of 6-12; At least 18 years old; Gavage tolerance in the first 24 hours after traumatic brain injury; Exclusion criteria: Comorbidities, such as uncontrolled Diabetes mellitus (BS sugar more than 200 mg / dL at the time of admission); Acute myocardial infarction in the last 48 hours, Acute or chronic renal failure; creatinine clearance less than 30 cc per minute; Liver disease, ALT, AST more than three to five times normal or having a previous history; Autoimmune disorders ; malignant diseases

##### Intervention groups

Intervention group: they will receive 30 mg of memantine tablets, twice a day, for a week within 24 hours of receiving. Control group: they will receive placebo tablets With the same dose and order of group  
1. All patients will receive standard traumatic brain injury

treatment.

##### Main outcome variables

GCS alertness score; NSE-specific enzyme enzyme neurons (NSE)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100107003014N25**

Registration date: **2021-09-19, 1400/06/28**

Registration timing: **retrospective**

Last update: **2021-09-19, 1400/06/28**

Update count: **0**

##### Registration date

2021-09-19, 1400/06/28

##### Registrant information

##### Name

Shahram Ala

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1354 3083

##### Email address

sala@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-22, 1399/05/01

##### Expected recruitment end date

2021-09-01, 1400/06/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of memantine and placebo on NSE and GCS of traumatic brain injury patients: a randomized double blind, placebo controlled clinical trial

**Public title**

Comparison of the effect of memantine on NSE and GCS among traumatic brain injury patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Traumatic brain injury (TBI) Glasgow Coma Scale (GCS) between 6-12 Being at the age of 18 years old and above The patient can tolerate the drug in the first 24 hours after traumatic brain injury

**Exclusion criteria:**

Diabetes mellitus, uncontrolled (random blood sugar greater than 200 mg / dL at the time of administration) Acute myocardial infarction in the last 48 hours Acute or chronic renal failure, creatinine clearance less than 60 ml per minute Autoimmune disorders and malignant diseases

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Considering the inclusion criteria, 60 eligible samples will be selected by available sampling method. The process of random allocation of patients will be done by blocking with random allocation software at the address: <https://random-allocation-software.software.informer.com/2.0/>. The number of 15 quadruple blocks will be determined with the help of software. Participants will be randomly assigned to the study groups according to block randomization with 4 patients in each block.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participating patients, principal investigator (supervisor and assistant), healthcare staff (physicians, nurses), data collection assistant, and those evaluating the outcome

are unaware of the type of intervention being assigned. The appearance and packaging of the drug and placebo are similar.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

-

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

**Street address**

Faculty of Pharmacy, Payambar Azam University Complex, Farahabad Road

**City**

Sari

**Province**

Mazandaran

**Postal code**

4847193698

**Approval date**

2020-07-08, 1399/04/18

**Ethics committee reference number**

IR.MAZUMS.REC.1399.473

**Health conditions studied****1****Description of health condition studied**

Traumatic brain injury

**ICD-10 code**

S06

**ICD-10 code description**

Intracranial injury

**Primary outcomes****1****Description**

neuron-specific enzyme (NSE)

**Timepoint**

Days 1, 3 and 7

**Method of measurement**

Laboratory test

**2****Description**

Glasgow coma scale

**Timepoint**

Days 1, 3 and 7

**Method of measurement**

clinical

**Secondary outcomes****1****Description**

Survival / Death

**Timepoint**

3 months later

**Method of measurement**

Phone call with patient

**Intervention groups****1****Description**

Intervention group1: 30 mg tablet Memantine , twice daily until one week

**Category**

Treatment - Drugs

**2****Description**

Control group: Placebo, 30 mg tablet, twice daily until one week

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital in Sari

**Full name of responsible person**

Shahram Ala

**Street address**

Razi street

**City**

Sari

**Province**

Mazandaran

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Majid Saeedi

**Street address**

Vice Chancellor for Research and Technology;  
Moallem square

**City**

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pajoheshi@mazums.ac.ir

**Grant name**

Thesis research project

**Grant code / Reference number**

8022

**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**

Shahram Ala

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

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Faculty of Pharmacy, Payambar Azam University  
Complex -18th km of Farahabad road

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## Person responsible for scientific inquiries

### Contact

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Professor  
**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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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