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)

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+98 15 1354 3083

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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
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Province
Mazandaran
Postal code
4816633133
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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
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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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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