Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Neuroprotective effects of memanthine in patients with traumatic brain injury

Protocol summary

Summary

The purpose of this study is evaluation of neuroprotective effects of memantine in adult patients with traumatic brain injury. In this randomized clinical trial,40 patients will be recruited from department of neurosurgery and intensive care unit , Imam Hussein hospital, Tehran, Iran. After randomization of the subject,20 subjects in group A will receive memantine 30mg twice daily for 7days and 20 subjects in group B will be followed as control group. Outcome measures include: Change in neuron specific enolase (NSE) from baseline to days 3 and 5 (time frame: baseline, 3 days and 5 days after intervention) Secondary outcome measures: 1- Change in Glasgow Coma scale (GCS) from baseline to day 5 (time frame: baseline and 5 days after intervention) 2-Comparison of mortality rate 3 months after intervention in two groups 3-Evaluation of relationship between neuron specific enolase level and mortality rate 4- Evaluation of relationship between neuron specific enolase level and GCS

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013022610178N4**
Registration date: **2013-05-07, 1392/02/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-05-07, 1392/02/17

Registrant information

Name

Mohammad Sistanizad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 0087

Email address

sistanizadm@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-05-05, 1392/02/15

Expected recruitment end date

2014-03-06, 1392/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Neuroprotective effects of memanthine in patients with traumatic brain injury

Public title

Effects of memanthine in traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients with traumatic brain injury exclusion criteria: hemorrhagic stroke; sensitivity to memantine; acute or chronic renal failure; acute or chronic hepatic disease; acute MI (<48 hours); autoimmune diseases; administration of memantine during 6 months before stroke

Age

From **18 years** old to **149 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University of Medical Sciences
Street address
Velenjak Street, Shahid Chamran High Way
City
Tehran
Postal code
Approval date
2012-04-03, 1391/01/15
Ethics committee reference number
90-1-94-8104

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 enolase
Timepoint
Day 1,3,5
Method of measurement
Elisa kits

Secondary outcomes

1

Description
Glasgow Coma scale
Timepoint
fraom day 1 for 7days
Method of measurement
Examination

2

Description
mortality
Timepoint
90 days after trauma
Method of measurement
Will be checked by phone

Intervention groups

1

Description
Memantine 20 mg three times per day for 7 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Neurosurgery, Imam Hussein medical center
Full name of responsible person
Mohammad Sistanizad
Street address
Shahid Madani Street
City
Tehran

2

Recruitment center
Name of recruitment center
Intensive care unit, Imam Hussein medical center
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person

Tahereh Shams

Street address

Velenjak Street, Shahid Chamran High Way

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor / Clinical Pharmacy Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty