Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Memantine versus Placebo on the Outcome and Functional Recovery of Patients with Intracranial hemorrhage: a double-blind randomized placebo-controlled pilot trial

Protocol summary

Summary

The aim of this study is to evaluate the effect of memantine on the outcome of patients with Intracranial Hemorrhage (ICH). The present study is a double-blind randomized placebo-controlled pilot trial. Patients with ICH will be enrolled base on the inclusion criteria. Written informed consent will be obtained from all patients or patient's family before enrollment in the study. Participates will randomly be divided into two groups, using random block. One group will receive a 10 mg memantine for the first month, starting during the first 24 hours following ICH, and then 20 mg for the next two months. The other group will receive a placebo in the same way as the active drug. Patient will be excluded if any adverse effect happens due to medication. Baseline neurological and functional status of patients will be evaluated using National Institute of Health Stroke Scale Criteria (NIHSS), Glasgow Outcome Scale (GCS), Modified Rankin Scale (MRS), Barthel Index (BI) and Fugl-Meyer (FM) at the time of admission. Brain CT scan will be performed on the day of admission, 72 hours after drugs administration and on 7th day to assess the size of hematoma and prihematoma edema. Mortality rate, neurological status and functional recovery will be evaluated over three months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305128490N2**
Registration date: **2013-05-19, 1392/02/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-05-19, 1392/02/29

Registrant information

Name

Seyed Mohammad Seyed Saadat

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

00983221572-00983223856

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Recruitment status

Recruitment complete

Funding source

Deputy of research, Guilan University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Memantine versus Placebo on the Outcome and Functional Recovery of Patients with Intracranial hemorrhage: a double-blind randomized placebo-controlled pilot trial

Public title

Effect of Memantine on the Outcome of Patients with Intracranial hemorrhage

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: 1. Patients with the diagnosis of first ever, spontaneous, non-traumatic supratentorial ICH confirmed by a clinical examination and radiological findings 2. Admission NIHSS <20 3. Patients whom diagnosis is made within less than 6 hours after onset of symptoms 4. Patients with a length of hospital stay of at least 7 days 5. Age <80 6. Admission GCS >5 7. Admission hematoma volume <30 cc Patients who will not include: 1.Those with previous or concomitant ischemic stroke 2.Those with other systemic disease including liver or kidney failure 3. Those who have pace maker, or suffer from severe neuropathy, systemic vascular disease or major affective disorders. 4. Those with a positive history of severe disability due to neurological or non-neurological causes 5.Those with a previous history of ICH, myocardial infarction or ischemic stroke 6. Those who abuse alcohol 7. Those with confirmed diagnosis of cognitive disorders based on DSM-IV criteria for dementia or IQCODE questionnaire 8. Those with ICH secondary to brain trauma or rupture of brain aneurysm 9. Those with a history of using anticoagulant drugs, antiplatelet drugs and NSAIDs. 10. Pregnant patients 11. Those with concomitant Intraventricular hemorrhage (IVH) 12.Deep coma Exclusion criteria: 1. Refusal to continue with the study 2. The occurrence of serious adverse drug affects at any time during the study. 3. Alcohol abuse during the study period

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Student Research Comittee, Deputy of research, Across Sepah bank, West shahid beheshti bolvard,Gas square

City

Rasht

Postal code

Approval date

2013-02-09, 1391/11/21

Ethics committee reference number

1910396403

Health conditions studied

1

Description of health condition studied

Intracerebral haemorrhage

ICD-10 code

I61.2

ICD-10 code description

Intracerebral haemorrhage in hemisphere, unspecified

Primary outcomes

1

Description

Mortality

Timepoint

During the three-month follow-up period

Method of measurement

Mortality rate

2

Description

Functional recovery

Timepoint

On admission, 7th day, and on discharge

Method of measurement

National Institute of Health Stroke Scale(NIHSS)

3

Description

Motor recovery

Timepoint

On admission, 7th day, on discharge, and 3 month later

Method of measurement

Fugl-Meyer (FM)

4

Description

disability

Timepoint

On admission, 7th day, on discharge, and 3 month later

Method of measurement

modified Rankin Scale(mRS)

5

Description
Performance in basic Activities of Daily Living
Timepoint
On admission, 7th day, on discharge, and 3 month later
Method of measurement
Barthel index (BI)

6

Description
Level of consciousness
Timepoint
On admission, 7th day, and on discharge
Method of measurement
Glosgow coma scale (GCS)

Secondary outcomes

1

Description
Changes in the size of hematoma
Timepoint
On admission, 72 hours later, and 7th day
Method of measurement
Based on the findings of CT scan

2

Description
Changes in the size of perihematomal edema
Timepoint
On admission, 72 hours later, and 7th day
Method of measurement
Based on the findings of CT scan

Intervention groups

1

Description
Memantine , 10 mg oral pill daily for the first month and 20mg forthe next two months
Category
Treatment - Drugs

2

Description
Placebo, 10 mg oral pill daily for the first month and 20mg for the next 2 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Poursina Hospital, Guilan Trauma Research Center
Full name of responsible person
Dr Babak Bakhshayesh Eghbali
Street address
Poursina Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of research, Guilan University of Medical Sciences
Full name of responsible person
Dr Abdolrasool Sobhani
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Student Research Comittee, Deputy of research, Across Sepah bank, West shahid beheshti bolvard,Gas square
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Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of research, Guilan 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
Guilan University of Medical Science
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Person responsible for updating data

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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