

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

effectiveness of amantadine hydrochloride on functional recovery in sever traumatic brain injury

Protocol summary

Study aim

effectiveness of amantadine hydrochloride on functional recovery in sever traumatic brain injury

Design

This study was conducted in a randomized clinical trial on 60 patients with brain trauma.

Settings and conduct

This study will be carried out at Tabriz Imam Hospital in a three-blind manner, only the head nurse will be aware of it, and the researcher and the patient and Analzor will be unaware of it.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1- Patients aged 18 to 65 years 2. People who have not had a known illness before head injury. 3. The subject matter of the dispute shall provide his written consent on his behalf Exit criteria: People with severe cardiovascular disease or congestive heart failure, myocardial infarction, persistent spinal cord injury, cancer, or any other severe disease that affects the evaluation of treatment. People with chronic steroid therapy Individuals received any other drug within 30 days of injury. Significant TBI, brain tumor, cerebrovascular event, or other persistent brain illusions

Intervention groups

Patients aged 18 to 65 years with severe brain trauma will receive twice daily Amantadine 100 mg daily after an accident, and this dose will continue for 11 days. At week 3, the dose will be increased to 150 mg twice a week and at week 4 to 200 mg twice a week.

Main outcome variables

Mini-mental Status Test (MMSE) for patients with severe acute traumatic brain injury

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120527009878N7**

Registration date: **2019-05-16, 1398/02/26**

Registration timing: **prospective**

Last update: **2019-05-16, 1398/02/26**

Update count: **0**

Registration date

2019-05-16, 1398/02/26

Registrant information

Name

Firooz Salehpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 0830

Email address

salehpourf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-16, 1398/03/26

Expected recruitment end date

2019-09-01, 1398/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effectiveness of amantadine hydrochloride on functional recovery in sever traumatic brain injury

Public title

effectiveness of amantadine hydrochloride on functional recovery in sever traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1- Patients aged 18 to 65 years 2. Those who have not had a known disease prior to head injury. 3. The supervisor will provide his written consent on his behalf

Exclusion criteria:

1-People with severe cardiovascular disease or congestive heart failure, myocardial infarction, persistent spinal cord injury, cancer, or any other severe disease that affects the evaluation of treatment. 2-People with chronic steroid therapy 3-Individuals received any other drug within 30 days of injury. 4-Significant TBI, brain tumor, cerebrovascular event, or other persistent brain illnesses

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The accident will be the case with two boxes, each containing blue and red cards, one of which represents a placebo and the other representing Amantadine, and only the head nurse of Tabriz Imam Reza Hospital and the medical staff of This will be known and will place one of the colored stickers in the patient's case. Three months later, the examiner will examine the patient without notifying which treatment method has been chosen and will record the patient's radiological criteria.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The selected patients will be divided into two groups of placebo recipients and amantadine recipients based on the color of the card, which the head nurse will be informed of. The next month, the examiner examined the patient without knowing which treatment method was selected, and the radiological criteria It will be recorded for the patient, which is also a type of treatment methodology, and therefore on this basis, the study will be blinded to three parts, and after the analysis, the head and nurse will be asked the type of blue and red method.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz Medical School

Street address

Azadi Ave , Golghast St , Imam Reza Hospital

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2019-05-07, 1398/02/17

Ethics committee reference number

IR.TBZMED.REC.1398.121

Health conditions studied

1

Description of health condition studied

Level of consciousness and cognitive function in patients with trauma

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mini-mental Status Test (MMSE) scoring for patients with severe acute trauma

Timepoint

During surgery and duration of hospitalization after surgery

Method of measurement

Check out the Mini-mental Status Test (MMSE) table.

2

Description

Disability Rating Scale (DRS) scoring for patients with severe acute traumatic brain injury

Timepoint

During surgery and duration of hospitalization after surgery

Method of measurement

Disability Rating Scale (DRS) Score

3

Description

Glasgow Outcome Scale Scoring (GOS) for patients with

severe acute traumatic brain injury

Timepoint
During surgery and duration of hospitalization after surgery

Method of measurement
Check Glasgow Outcome Scale Table (GOS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients aged 18 to 65 years with severe brain trauma will receive twice daily Amantadine 100 mg once a day, and this dose will continue for 11 days. At week 3, the dose will be increased to 150 mg twice a week and week 4 to 200 mg twice weekly.

Category
Treatment - Drugs

2

Description
Control group: Patients aged 18 to 65 years with severe brain trauma will receive placebo once a day after an accident at a dose of 100 mg of amantadine twice daily and will continue for 11 days. At week 3, the dose will be increased to 150 mg twice a week and at week 4 to 200 mg twice a week.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Ahsan Rahimi

Street address
Azadi St., Golghast St

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Phone
+98 44 1333 8507

Email
mshimiya@yahoo.com

Web page address
<https://imamreza.tbzmed.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mohammad Shimia

Street address
Azadi St., Golghast St

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Phone
+98 44 1446 9326

Email
Mshimia@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz 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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Moslem Shakeri

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

Street address
Golgashst ave

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Phone

+98 44 1333 8507

Email

shakerim@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ahsan Rahimi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Golgasht ave

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 44 1343 8707

Email

Rahimiahsan@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ahsan Rahimi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Golgasht ave

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 44 1333 8507

Email

ahimiahsan@yahoo.com

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