# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## effectivness of amantadine hydrocholoride on functional recovery in sever traumatic brain injery

### Protocol summary

**Study aim**
effectivness of amantadine hydrocholoride on functional recovery in sever traumatic brain injery

**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**

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Firooz Salehpour

**Name of organization / entity**

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Iran (Islamic Republic of)

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**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**
effectivness of amantadine hydrocholoride on functional recovery in sever traumatic brain injery

**Public title**
effectivness of amantadine hydrocholoride on functional recovery in sever traumatic brain injery

**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 illusions
**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 Resa 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

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Azadi St., Golghast St

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mohammad Shimia

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**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

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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