

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of amantadine on the recovery of patients with severe brain injury: a randomized controlled clinical trial

Protocol summary

Study aim

Determining the effect of amantadine on the recovery of patients with traumatic brain injury

Design

clinical trial with an intervention group, with a parallel group; Three-blind, phase 3, sample size 102, randomized using block method

Settings and conduct

This study is conducted in Imam Reza Birjand Hospital, South Khorasan Province. 102 patients are divided into two intervention groups one or two (A-B) in a simple random manner. Glasgow Coma Criteria will be evaluated before the intervention and 3 and 7 days after the intervention.

Participants/Inclusion and exclusion criteria

Our study population will be patients with traumatic brain injury whose GCS ≤ 8 admitted to the Neurosurgery ICU of Imam Reza (AS) Birjand Hospital in 1401. Inclusion criteria 1) Age more than 16 years 2) Glasgow coma criteria less than 8 3) The possibility of receiving medicine through NG or OG tube 4) Obtaining consent from the patient to enter the study after he regains consciousness and recovers Exclusion criteria 1. Pregnancy 2. Diabetes disease, blood fat 3. Cancer 4. Congenital, ischemic and atherosclerotic heart disease 5. Kidney failure 6. Patients with unknown identity 7. Kidney disease 8. Use of dopanergic agents by the patient 9. Amantadine is a contraindication.

Intervention groups

Intervention groups: Group A will receive amantadine 100 mg twice a day (at 8 am 8 pm) for 6 weeks and control group B will receive a placebo containing fructose for 6 weeks.

Main outcome variables

Glasgow Coma Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043934N18**

Registration date: **2023-07-14, 1402/04/23**

Registration timing: **prospective**

Last update: **2023-07-14, 1402/04/23**

Update count: **0**

Registration date

2023-07-14, 1402/04/23

Registrant information

Name

Zabihullah Mohaghegh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3232 3232

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-22, 1402/05/31

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of amantadine on the recovery of patients with severe brain injury: a randomized controlled clinical trial

Public title

The effect of amantadine on the recovery of patients with traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age more than 16 years $GCS \leq 8$ Possibility of receiving medicine through NG or OG tube Obtaining consent from the patient to enter the study after she regains consciousness and recovers (مؤنث)

Exclusion criteria:

Pregnancy Diabetes disease Dyslipidemia Cancer Congenital, ischemic and atherosclerotic heart disease Kidney failure Patients with unknown identity Kidney disease Use of dopanergic agents by the patient Contraindications for the use of amantadine

Age

From 16 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: 51

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups by simple randomization and block method: 1. Amantadine recipient (A) and 2. Placebo recipient (B). The selection and placement of patients in two groups will be simple random and blocked in a closed and sealed envelope. In this way, various quadruple blocks are created first (AABB, BBAA, ABAB, BABA, ABBA and BABA). One of these blocks will be randomly selected and the patients will be divided into one of two groups A or B. Then randomization is done for other patients as well.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participant in the study: due to the fact that the patients are not conscious, they will not know about the prescribed medicine for them. Outcome evaluator: The study administrator, without knowing the type of drug received, asks questions from the patients and records them in the relevant checklist. Analyst: The person who is responsible for data analysis will not know about the placement of patients in each group and the data will be analyzed blindly.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand Town

City

Birjand

Province

South Khorasan

Postal code

9717811674

Approval date

2022-07-24, 1401/05/02

Ethics committee reference number

IR.BUMS.REC.1401.179

Health conditions studied

1

Description of health condition studied

brain injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes

1

Description

Glasgow Coma Scale

Timepoint

First and before the intervention, the third day of the intervention and the seventh day of the intervention

Method of measurement

Using the Glasgow coma criteria table and clinical examination by a neurosurgery assistant

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first intervention group: Group A receiving amantadine 100 mg twice a day (8:00 a.m. to

8:00 p.m.) for 6 weeks.

Category

Treatment - Drugs

2

Description

Control group: The first control group: Group B receiving placebo containing fructose for 6 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Birjand Hospital

Full name of responsible person

Zabihullah Mohaqiq

Street address

School of Medicine, Birjand University of medical sciences, Ghahhari Blvd,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Zabihullah Mohaqiq

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

General Practitioner

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Subspecialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no need to publish individual patient information

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