Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

Evaluation the Effect of N-acetylcysteine as a Neuroprotective in Traumatic Brain Injury Patients with Moderate to Severe Consciousness Level Admitted to Intensive Care Unit

Protocol summary

Study aim
Evaluation the effect of N-acetylcysteine as a neuroprotective in traumatic brain injury patients with moderate to severe consciousness level admitted to intensive care unit.

Design
Randomised, controlled, parallel group trial with blinded outcome assessment. Randomisation was centralised with simple randomization with random number tables

Settings and conduct
Twenty eight patients in age group 18 to 65 years are randomly divided by random number tables into intervention (N-acetylcysteine) and control groups (n=14 cases). Researchers responsible for data collection and analyses are blind to the groups allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria are age range 18 – 65 year, consciousness level 9-12 based on GCS and transferred to intensive care unit less than 24 hours after trauma; The exclusion criteria are allergic reaction to N-acetylcysteine, stay in intensive care unit less than 72 hours, pregnant patients, associated spinal cord injury, craniotomy and history of autoimmune diseases.

Intervention groups
In the Intervention group, oral N-acetylcysteine with dose of 600 mg will be prescribed twice a day. In the control group, placebo (medical plaster powder) with dose of 600 mg will be prescribed twice a day.

Main outcome variables
Consciousness level based on GCS will recorded upon arrival, two days, 1, 2, 3 and 4 weeks after the drug administration and will compared between the two groups. Duration of hospitalization, the time required for mechanical ventilation and rate of mortality will compared between the two groups.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190725044331N1**
Registration date: **2019-09-06, 1398/06/15**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-06, 1398/06/15**
Update count: **0**

Registration date
2019-09-06, 1398/06/15

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-08-23, 1398/06/01
Expected recruitment end date
2020-02-20, 1398/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the Effect of N-acetylcysteine as a Neuroprotective in Traumatic Brain Injury Patients with Moderate to Severe Consciousness Level Admitted to Intensive Care Unit

Public title
Evaluation the Effect of N-acetylcysteine in Traumatic Brain Injury Patients with Moderate to Severe Consciousness Level Admitted to Intensive Care Unit

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age range 18 – 65 year Consciousness level 9-12 based on Glasgow Coma Scale (GCS) Transferred to intensive care unit less than 24 hours after trauma

Exclusion criteria:
Allergic reaction to N-acetylcysteine Stay in intensive care unit less than 72 hours Pregnant patients Associated spinal cord injury Craniotomy History of autoimmune diseases

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

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals are randomly divided into two groups based on simple randomization method using random digits table. In this method, a collection of non-template numbers is randomly generated and arranged as a table. Even numbers for the intervention group and the odd numbers for the control group are considered. According to the number of patients, they are randomly assigned to one of the treatment or intervention groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
Responsible for collecting data and data analyzer are blinded to patient's group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences

Street address
Research deputy, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

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Province
Khouzestan

Postal code
6135715794

Approval date
2019-02-02, 1397/11/13

Ethics committee reference number
IR.AJUMS.REC.1397.818

Health conditions studied

1

Description of health condition studied
Traumatic Brain Injury (TBI)

ICD-10 code
S06.9

ICD-10 code description
Unspecified intracranial injury

Primary outcomes

1

Description
Consciousness level

Timepoint
Upon arrival, two days,1, 2, 3 and 4 weeks after the drug administration

Method of measurement
Glasgow Coma Scale (GCS)

2

Description
Duration of hospitalization

Timepoint
Duration of admission to discharge

Method of measurement
day

3

Description
The time required for mechanical ventilation

Timepoint
Duration of hospitalization

Method of measurement
day

4

Description
Rate of mortality
Timepoint
Up to 4 weeks after the drug administration
Method of measurement
The number of patients who died

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Oral N-acetylcysteine with dose of 600 mg will be prescribed twice a day.
Category
Treatment - Drugs

2

Description
Control group: Placebo (medical plaster powder) with dose of 600 mg will be prescribed twice a day.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital, Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
PAIN-9717
Grant code / Reference number
330094137
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
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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