

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

Name

Mehdi Ebrahimi monfared

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3374 3037

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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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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

Farhad Soltani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi, PhD

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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

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ebrahimi Monfared

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Assistant professor

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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

Person responsible for updating data

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Name of organization / entity

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Position

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