

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Investigating the effect of N-acetylcysteine on the prognosis of patients with moderate to severe traumatic brain injury who referred to the Hafte Tir Hospital from October 1402 to October 1403

Protocol summary

Study aim

We decided to investigate the effect of acetylcysteine NAC on TBI patients and to investigate its effectiveness to reduce the side effects of TBI.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized block type, phase 3 on 60 referring patients from October 1402 to October 1403

Settings and conduct

This study was in the form of a clinical trial, in which it was a double-blind study of patients with moderate to severe traumatic brain injury who referred to the 7th Hospital from October 2023 to October 2024 randomly divided into two groups A and B, and NAC drug with an oral dose 3.6 grams for 4 days and then 1.8 mg for 3 days were given to the patients and a placebo drug group was given in an unspecified manner for the researchers and clinical nurses of the patients. (To each of the groups The study subject is given a drug (placebo or NAC) and the type of drug given remains in a sealed envelope until the end of the study, and at the end and after data analysis, the envelopes are returned to determine the type of drug given to each group)

Participants/Inclusion and exclusion criteria

Patients over 18 years of age with moderate to severe traumatic brain injury should refer to Haftam Tir Hospital from October 2023 to October 2024 . If the Glasgow coma scale is 3, they are not included in the study

Intervention groups

NAC with an oral dose of 3.6 grams for 4 days and then 1.8 mg for 3 days was given to the patients in the intervention group, and placebo was given to the control group. Then the level of consciousness of the patients is re-evaluated after 7 days and the outcome of the use of medicine is evaluated.

Main outcome variables

The effect of N-acetylcysteine on the prognosis of

patients with moderate to severe traumatic brain injury

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230815059150N1**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **prospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

Registration date

2023-09-02, 1402/06/11

Registrant information

Name

Mohammad Hossein Ghazvini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2246 5720

Email address

ghazvinimohammadhossein@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-22, 1402/06/31

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of N-acetylcysteine on the prognosis of patients with moderate to severe traumatic brain injury who referred to the Hafte Tir Hospital from October 1402 to October 1403

Public title

Effect of N-acetylcysteine in moderate to severe traumatic brain injury

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with moderate to severe traumatic brain injury
Patients over 18 years of age

Exclusion criteria:

Patients with Glasgow Coma Scale 3

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done in the form of standard block randomization and the use of sealed envelopes in such a way that each patient referred to the study entry conditions is numbered starting from 1 and then divided into two groups A and B is divided and then medicine or placebo is given to each of these groups. After studying the sealed envelope, it is returned for data analysis and it is determined which group was given medicine and which group was given placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the blinding method is double-blind, in which the patient, the clinical caregiver, and the researcher are kept blind, in this way that after randomizing the patients with the block randomization method, the people mentioned above is unknown about receive either the drug or the placebo therapeutic intervention of each group A and B . After collecting the data, the sealed envelope that specifies the type of therapeutic intervention is opened by the data analyst

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

Hemat Highway next to Milad Tower

City

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2023-08-28, 1402/06/06

Ethics committee reference number

IR.IUMS.FMD.REC.1402.267

Health conditions studied**1****Description of health condition studied**

Traumatic Brain Injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes**1****Description**

The effect of NAC on the Glasgow Coma Scale (GCS) of patients with moderate to severe traumatic brain injury

Timepoint

7 Days

Method of measurement

table of Glasgow Coma Scale

2**Description**

The effect of NAC on the Glasgow Outcome Scale (GOS) of patients with moderate to severe traumatic brain injury

Timepoint

7 Days

Method of measurement

Table of Glasgow Outcome Scale

3**Description**

The effect of NAC on the Modified Rankin Scale (mRS) of patients with moderate to severe traumatic brain injury

Timepoint

7 days

Method of measurement

Table of Modified Rankin Scale (mRS)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: N-acetylcysteine (NAC) drug is given to patients orally with an oral dose of 3.6 grams for 4 days and then 1.8 mg for 3 days.

Category

Treatment - Drugs

2**Description**

Control group: The placebo is taken orally and the same as the intervention group

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Haft Tir Martyrs Hospital

Full name of responsible person

Mohammad Hossein Ghazvini

Street address

Haft Tir Martyrs Hospital , End of the shahid Rajaei Expey, Rey

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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No.44 , Kangan Ave, Kangan Blvd , Artesh Blvd

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Mohammad Hossein Ghazvini

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

This study will be blinded for the patient and the researcher. After assigning people to the arms, the type of intervention on the person's questionnaire will be in the form of options A (main intervention) and B (control intervention) and the analyst will report the results as a difference between the two groups A and B after completing the analysis. will give and then the sealed envelope that shows the type of intervention of each group will be opened. After data collection, data will be analyzed by SPSS ver. 25 statistical software. Continuous quantitative variables will be reported by central dispersion indices (mean and standard deviation). K-S test will also be used to determine the normality of data distribution. Student T Test and Chi Square Test will be used for analysis between groups. $P < 0.05$ will be considered as a significant level for all tests

When the data will become available and for how long

Start access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

To refer the contents

From where data/document is obtainable

Mohammad Hossein Ghazvini mobile number 09128882826 and 02122465720 and ghazvinimohammadhossein@gmail.com and address in Tehran, Shahr-e Rey , Haftome Tir Hospital

What processes are involved for a request to access data/document

After receiving the request and not inconsistent with the information received, the data will be sent to the applicant within 2-3 business days

Comments