Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 2024randomly 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
۱۴۴۹۶۱۴۵۳۵

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohammad Hossein Ghazvini
Street address
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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Person responsible for updating data

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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