Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Clinical trial to evaluate the effect of N-acetylcysteine (NAC) in patients with moderate traumatic brain injury (MTBI)

Protocol summary

Summary

In this study we will investigate the effect of N-acetylcysteine(NAC) on mild traumatic brain injury(MTBI). In this randomized, double-blinded, placebo controlled-Phase III trial, randomizationof 104 patients with MTBI will be performedby random number tables. Initial diagnosis will be determined by the results of physical examination and CT scan. Inclusion criteria includes patients older than 18 years with MTBI and a score between 9–13 on the Glasgow Coma Scale(GCS). Patients are excluded who have consumed alcohol or used narcotics at anytime while diagnosed with MTBI. Patients who show an allergic reaction to NAC will also be excluded from the study. During the treatment, as part of the routine, the physician will assess the level of consciousness by checking eye pupils and GCS. Blood samples will be taken from patients and initial level of blood antioxidant enzymes (SOD, GPX) will be recorded in the checklist. An hour after admission, treatment group (52 patients) will receive infusion of NAC 150mg/kg in 200ml Glucose5% over a 30minute period. The control group (52 patients) will receive infusion of 200 cc serum distilled water 5% over a 30 minute period. Patients and the doctor who records the results were unaware of the form of interventions. Both treatment and placebo group will be re-sampled six hours after the first dose and the results will be recorded. If the investigated factors increase, response to treatment will be marked positive. It is estimated thata year and six months will be required for the completion of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010131709N1**
Registration date: **2017-03-05, 1395/12/15**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-03-05, 1395/12/15

Registrant information

Name
Ayat Ghasemi
Name of organization / entity
Arak University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

In this study, the cost of drugs provided by Vice chancellor for research, Arak University of Medical Sciences.

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to evaluate the effect of N-acetylcysteine (NAC) in patients with moderate traumatic brain injury (MTBI)

Public title

The effect of N-acetylcysteine (NAC) in patients with

moderate traumatic brain injury (MTBI)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients older than 18 years old.; patients with moderate traumatic brain injury; The GCS between 9 and 13; Filling out the informed consent form by the patient or the accompanies. Exclusion criteria: Unwillingness to participate in the study; Patients who have consumed alcohol or used narcotics at anytime while diagnosed with MTBI; Patients who showed an allergic reaction to NAC

Age

From **18 years** old to **120 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Valiasr Hospital

City

Arak

Postal code

Approval date

2016-06-13, 1395/03/24

Ethics committee reference number

Ir.arakmu.rec.1395.97

Health conditions studied

1

Description of health condition studied

Traumatic brain injury

ICD-10 code

S06.1

ICD-10 code description

Traumatic cerebral oedema

Primary outcomes

1

Description

Superoxide dismutase

Timepoint

Before treatment, six hours after the first dose

Method of measurement

Blood samples will be taken from patients and initial values of blood antioxidant enzymes: (Superoxide dismutase U/ml) will be recorded in the checklist.

2

Description

Glutathione peroxidase

Timepoint

Before treatment, six hours after the first dose

Method of measurement

Blood samples will be taken from patients and initial values of blood antioxidant enzymes: (Glutathione peroxidase U/l) will be recorded in the checklist.

Secondary outcomes

empty

Intervention groups

1

Description

The treatment group : Patients will receive N-acetylcysteine (NAC) 150mg/kg in 200ml Glucose5% over a 30 minute time period.

Category

Treatment - Drugs

2

Description

The control group: Patients will receive 200 cc serum distilled water 5% over a 30 minute time period.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Ayat Ghasemi

Street address
Valiasr Hospital, ValiAsr Square, Arak
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Arak University of Medical Sciences
Full name of responsible person
Hasan Haherahmadi
Street address
Arak University of Medical Sciences, Sardasht, Arak
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty