

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of L-Carnitine on inflammatory biomarker level of NSE (Neurone specific Enolase) in traumatic brain injury patients

Protocol summary

Summary

The aim of the study is to evaluate the effect of L-carnitine on NSE in patients with traumatic brain injury. Inclusion criteria are patients aging 18-75 years with traumatic brain injury in last 24 hours. Exclusion criteria are patients with diarrhea, abdominal cramps, kidney failure undergoing dialysis, history of heart disease and history of sensitivity to L-carnitine. After approval of the ethical committee of the university and taking an informed consent, 40 patients diagnosed with DAI (Diffuse axonal injury) will be admitted. All patients will receive standard treatment based on the type of trauma. They will also receive assistance therapy. They will randomly be divided into two groups. The first group will receive standard and common treatment. They will also receive enteral L-carnitine 1g/12hr. The second group will receive standard treatment plus placebo. The study will take on for a week. During this time, the vital signs and patient information will be recorded. All patients will have CTscan. Then it will be replicated based on the clinical situation during the study. Blood samples will be taken from all patients on the zero day (after trauma) and the 3rd and the 7th days, and will be evaluated by NSE kit. Cognitive and behavioral complication, findings of brain CT scan, signs of hemodynamics, length of hospital stay will be recorded at one and three month intervals after discharge.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410312582N9**
Registration date: **2014-12-22, 1393/10/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-22, 1393/10/01

Registrant information

Name

Ata Mahmoodpoor

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Research deputy of Tabriz University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of L-Carnitine on inflammatory biomarker level of NSE (Neurone specific Enolase) in traumatic brain injury patients

Public title

Effect of L-carnitine inpatients with traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients aging 18-75 years with

traumatic brain injury in last 24 hours Exclusion criteria:having brain trauma in more than previous 24 hours; diarrhea; abdominal cramps; patients with kidney failure undergoing dialysis; history of heart disease; history of sensitivity to L-carnitine; having other traumas such as organic trauma; hypertension; alcoholic cirrhosis

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Tabriz University of Medical Sciences

Street address

Golgasht street

City

Tabriz

Postal code

Approval date

2014-08-06, 1393/05/15

Ethics committee reference number

5/4/5598-9395

Health conditions studied

1

Description of health condition studied

Traumatic Brain Injury

ICD-10 code

G93.6

ICD-10 code description

Cerebral oedema traumatic (S06.1)

Primary outcomes

1

Description

Glasgow Coma Scale(GCS)

Timepoint

1 week

Method of measurement

assay with GCS(Eye opening, limb movement, verbal)

Secondary outcomes

empty

Intervention groups

1

Description

In control group, all patients receive placebo every 12 hours as enteral feeding in addition to standard treatment for traumatic brain injury for one week.

Category

Placebo

2

Description

In intervention group, all patients receive L-carnithine 1 g/12hours as enteral feeding in addition to standard treatment for traumatic brain injury for one week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada hospital ICU

Full name of responsible person

Ata Mahmoodpoor

Street address

Shohada Hospital, El-goli street

City

Tabriz

2

Recruitment center

Name of recruitment center

General ICU of Imam Reza Hospital

Full name of responsible person

Ata Mahmoodpoor

Street address

Imam Reza Hospital, Golghasht street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Farhudi

Street address

Golgasht street

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research deputy of Tabriz 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

Name of organization / entity

Anesthesiology Department, Tabriz University of Medical Sciences

Full name of responsible person

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Director of ICU, Associate Professor

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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