

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The study of intravenous selenium effect in the outcome of patients with acute traumatic brain injury

Protocol summary

Summary

The aim of this investigation is whether the selenium has efficacy on functional recovery of patients with acute traumatic brain injury (TBI) or not. This study is a prospective, double-blind, unicenteric, phase 2 clinical trial. A total of 110 patients, 18 to 100 years of age, with moderate and severe acute traumatic brain injury (Glasgow Coma Scale score of ≤ 12) and at least one reactive pupil are randomly assigned to take daily selenium or placebo intravenous infusion in addition to standard treatment of TBI. The study treatment is initiated within the first 8 hours after brain injury and is continuing for the consecutive 14 days. The primary outcome is the patient functional recovery according to Extended Glasgow Outcome Scale (GOS-E), determined in the days 30 and 60 after brain injury. The secondary outcomes include mortality, level of consciousness, body organs function, selenium side effects, length of intensive care unit (ICU) stay and length of hospital stay.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090223865N1**

Registration date: **2016-01-14, 1394/10/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-14, 1394/10/24

Registrant information

Name

Shakiba Mozari

Name of organization / entity

Sabzevar University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of intravenous selenium effect in the outcome of patients with acute traumatic brain injury

Public title

The effect of selenium in the treatment of acute traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: moderate and severe traumatic brain injury according to Glasgow Coma Scale score 12 or less; 18 to 100 years of age; at least one reactive pupil; selenium initiated within 8 hours after brain injury. Exclusion criteria: Glasgow Coma Scale score 3; bilaterally fixed pupils; hypotension (systolic BP < 90 mmHg for ≥ 10 min); a life expectancy of less than 24 hours; spinal cord injury; pregnancy; only an isolated epidural hematoma; known case of renal failure.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

randomization based on the right number of national code(odd or even)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences; Hemmat Highway

City

Tehran

Postal code

Approval date

2015-08-09, 1394/05/18

Ethics committee reference number

IR.IUMS.rec.1394.9311692002

Health conditions studied

1

Description of health condition studied

acute traumatic brain injury

ICD-10 code

S06

ICD-10 code description

Intracranial injury

Primary outcomes

1

Description

Patient functional recovery

Timepoint

The days 30 and 60 after brain injury

Method of measurement

GOS-E(Extended Glasgow Outcome Scale)

Secondary outcomes

1

Description

Mortality

Timepoint

The first 24 hours after intensive care unit admission

Method of measurement

Acute Physiology and Chronic Health Evaluation3 score(APACHE3 score)

2

Description

Level of consciousness

Timepoint

Everyday from the first to 15th day of brain injury

Method of measurement

Full Outline Of UnResponsiveness(FOUR) Score

3

Description

Body organ function

Timepoint

Everyday from the first to 15th day of brain injury

Method of measurement

Sequential Organ Failure Assessment(SOFA) Score

4

Description

Selenium side effects(nausea, vomiting, nail changes, hair loss, tremor, garlic odor, flushing)

Timepoint

Everyday from the first to 15th day of brain injury

Method of measurement

Clinical exam

5

Description

Length of intensive care unit(ICU) stay

Timepoint

Everyday from ICU admission to discharge

Method of measurement

Days number

6

Description

Length of hospital stay

Timepoint

Everyday from hospital admission to discharge

Method of measurement

Days number

Intervention groups

1

Description

A total dose of 500µg intravenous(IV) selenium as a 30-min bolus injection followed by 500µg as a 24 hours IV infusion for the consecutive 14 days

Category

Treatment - Drugs

2

Description

sodium chloride 0.9% in the same regimen

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasoul Medical Complex

Full name of responsible person

Shakiba Mozari

Street address

Hazrat Rasoul Medical Complex, Niyayesh Street,
Sattarkhan Avenue

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Iran University of
Medical Sciences

Full name of responsible person

Dr. Seyed Ali Javad Moosavi

Street address

5th floor, Central Building, Iran University Of Medical
Science, Hemmat Highway

City

Tehran

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 Iran 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

Iran University of Medical Sciences

Full name of responsible person

Shakiba Mozari

Position

Intensive Care Fellowship

Other areas of specialty/work

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Web page address**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