Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 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

Iran (Islamic Republic of)

Phone

+98 51 4466 8481

Email address

mozarish@medsab.ac.ir

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

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Postal code

Phone

+98 21 86701

Fax

Email

"Mozarish@medsab.ac.ir"; "sh.mozari@gmail.com"

Web page address

Person responsible for scientific 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

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Postal code

Phone

+98 21 86701

Fax

Email

"Mozarish.medsab.ac.ir"; "sh.mozari@gmail.com"

Web page address

Person responsible for updating data

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
Street address
Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Postal code
Phone
+98 21 86701
Fax
Email
"Mozarish@medsab.ac.ir"; "sh.mozari@gmail.com"
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