Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative Evaluation of the Effects of Hypertonic Saline 5% Infusion vs Bolus on Traumatic Brain Biomarker S100B and Oxidative Stress Total antioxidant power (TAP), ROS (Reactive Oxygen Species) in Traumatic Brain Injury

Protocol summary

Summary

This study evaluates efficacy and safety of osmotic agents, mannitol as the first line agent for years Vs hypertonic saline solution 5% (HSS5%) (Bolus Vs infusion) in the treatment of high intracranial pressure (ICP) In adult Traumatic Brain Injury (TBI) with GCS = 3-12. In this study, 30 adult TBI with GCS = 3-12 are randomly assigned three groups to receive 125 cc HSS 5% as bolus for 1 hour Q 6 hr for 3 days, 500 cc HSS 5% as infusion Q 24 hr for 3 days, or manitol 20% as a bolus of 1 g/kg, repeated doses can be given at 0.25 to 0.5 g/kg every six hours as needed. Serum S100B, ROS, TAP HSS5% hemodynamic and coagulation profiles, serum sodium and potassium, and osmolarity levels will be evaluated at the baseline, and daily for 3 days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011055107N1**
Registration date: **2011-03-30, 1390/01/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-03-30, 1390/01/10

Registrant information

Name
Narjes Hendoiee
Name of organization / entity
Department of clinical pharmacy, Faculty of Pharmacy
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Iran (Islamic Republic of)
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+98 21 6695 4709
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Recruitment status

Recruitment complete

Funding source
Tehran University of Medical Sciences and Health Services

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Evaluation of the Effects of Hypertonic Saline 5% Infusion vs Bolus on Traumatic Brain Biomarker S100B and Oxidative Stress Total antioxidant power (TAP), ROS (Reactive Oxygen Species) in Traumatic Brain Injury

Public title

Effect of hypertonic saline 5% on elevated intracranial pressure in traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18 - 65 years, closed traumatic brain injury, GSC score 3-12, hemodianamically stable

(CVP<15 and MAP <65 mmhg), serum Na: 135-140meq/l, serum creatinin < 1.5 or urine output > 0.5 cc/hr, at least one reactive pupil, INR less than 1.5, Serum osmolality ≤ 320 mOsm/kg Exclusion Criteria: pregnancy, Penetrating trauma, spinal cord injury, Serum Na> 160meq/l or less than 135meq/l, Scr>1.5 mg/dl, ARF during the treatment

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences and Health Services

Street address
Qods Street, Enghelab Avenue, 1417863181

City
Tehran

Postal code
1417863181

Approval date
2009-01-09, 1387/10/20

Ethics committee reference number
w/88/1597/130

Health conditions studied

1

Description of health condition studied
Traumatic Brain Injury

ICD-10 code
S06

ICD-10 code description
S06.1,S06.2,S06.3,S06.4,S06.5,S06.6,S06.7,S06.8,S06.9

Primary outcomes

1

Description
s100B

Timepoint
baseline and after 1, 2, 3 days

Method of measurement
blood sampling and ELISA kit

2

Description
reactive oxygen species

Timepoint
baseline and after 1, 2, 3 days

Method of measurement
blood sampling and ELISA kit

3

Description
total antioxidant power

Timepoint
baseline and after 1, 2, 3 days

Method of measurement
blood sampling and ELISA kit

Secondary outcomes

1

Description
APACHE II score

Timepoint
baseline and every 6 hours for 4 days

Method of measurement
international table

2

Description
SOFA score

Timepoint
baseline and after 1, 2, 3 days

Method of measurement
international table

3

Description
Glasgow Coma Scale

Timepoint
baseline and after 1, 2, 3 days

Method of measurement
international table

4

Description
heart rate
Timepoint
baseline and after 1, 2, 3 days
Method of measurement
mmhg

5

Description
respiratory rate
Timepoint
baseline and after 1, 2, 3 days
Method of measurement
monitoring device in ICU

6

Description
Pottasium
Timepoint
baseline and after 1, 2, 3 days
Method of measurement
laboratory

7

Description
serum creatinine
Timepoint
baseline and after 1, 2, 3 days
Method of measurement
laboratory

8

Description
Temperature
Timepoint
baseline and after 1, 2, 3 days
Method of measurement
thermometer

9

Description
central vein pressure
Timepoint
baseline and after 1, 2, 3 days
Method of measurement
central vein pressure ruler

10

Description
mean arterial pressure
Timepoint
baseline and after 1, 2, 3 days
Method of measurement
(SPB+2DBP)/3

11

Description
Platelet count
Timepoint
baseline and after 1, 2, 3 days
Method of measurement
laboratory

12

Description
Hemoglobin
Timepoint
baseline and after 1, 2, 3 days
Method of measurement
laboratory

13

Description
White blood cell (WBC) count
Timepoint
baseline and after 1, 2, 3 days
Method of measurement
laboratory

14

Description
serum sodium
Timepoint
baseline and every 6 hour for 4 days
Method of measurement
laboratory

Intervention groups

1

Description
manitol 20% as a bolus of 1 g/kg, repeated doses can be given at 0.25 to 0.5 g/kg every six hours as needed
Category
Treatment - Drugs

2

Description
125 cc HSS 5% as bolus for 1 hour Q 6 hr for 3 days
Category
Treatment - Drugs

3

Description
500 cc HSS 5% as infusion Q 24 hr for 3 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of pharmacy, Tehran University of Medical Science and Health Services

Full name of responsible person

Dr Narjes Hendoiee-Pharm.D-Clinical pharmacy Resident

Street address

Department of clinical pharmacy , faculty of pharmacy,Tehran University of Medical Science and Health Services

City

Tehran

2

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Mojtaba Mojtahedzadeh-pharm.D-Full Professor-Fellowship in Critical Care – Clinical Pharmacy

Street address

Department of clinical pharmacy , faculty of pharmacy,Tehran University of Medical Science and Health Services

City

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3

Recruitment center

Name of recruitment center

Emam Khomeini Hospital Complex

Full name of responsible person

Dr Mohammad Taghi Beigmohammadi-MD- Assistant professor - Fellowship of Intensive Care

Street address

Anesthesiology & intensive Care Department , School of Medicine, Tehran University of Medical Science and Health Services

City

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4

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Arezoo Ahmadi-MD-Assistant professor -Fellowship of Intensive Care

Street address

Department of Anaesthesia, School of Medicine, Tehran University of Medical Science and Health Services

City

Tehran

5

Recruitment center

Name of recruitment center

Shohada Hospital-Tabriz University of Medical Science and Health Services

Full name of responsible person

Dr Ata Mahmoodpoor-MD-Assistant professor - Fellowship of Intensive Care

Street address

Anesthesiology & intensive Care Department - School of Medicine-Tabriz University of Medical Science and Health Services

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science and Health Services

Full name of responsible person

Fatemeh Saidi

Street address

Qods Street, Enghelab Avenue

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Science and Health Services

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

Department of clinical pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences and Heal

Full name of responsible person

Dr Narjes Hendoiee

Position

Pharm.D-Clinical Pharmacy Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Other areas of specialty/work

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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