

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6695 4709

##### Email address

hendoui@razi.tums.ac.ir

##### 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, hemodynamically 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**

Tehran

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**

Tehran

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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**Other areas of specialty/work****Street address**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Department of clinical pharmacy, Faculty of  
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**Position**

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**Other areas of specialty/work****Street address**

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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*