

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of effect of furosemide add on to hypertonic slain on neurohormonal factors in Traumatic brain injury,A randomized single blind clinical trial

#### Protocol summary

##### Summary

This study conducted for the evaluation of hypertonic saline osmotic therapy and added with furosemide in traumatic brain injury's patients. One group of 30 of the patients will be received 100 ml of hypertonic saline (NaCl 5%) as a loading dose, and then 20ml/h of infusion. Another group of 30 will be received 100 ml of hypertonic saline (NaCl 5%) and 40mg furosemide as a loading dose, and then 20ml/h of NaCl 5% and 0.05mg/kg/ h of furosemide as a 24 h infusion. Evaluation of serum sodium and its osmolarity, changes of S100B and NSE biomarker will be considered as management indicators. Hormonal alteration (Thyroid and Prolactin) will be considered as an evaluation of severity of the trauma and the effect of osmotic therapy to reduce hormonal alteration and prolonged function of the patients.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201509283014N10**  
Registration date: **2016-07-13, 1395/04/23**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-07-13, 1395/04/23

##### Registrant information

##### Name

Shahram Ala

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1354 3083

##### Email address

sala@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor of research, Mazandaran university of medical sciences

##### Expected recruitment start date

2016-04-18, 1395/01/30

##### Expected recruitment end date

2016-09-20, 1395/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of effect of furosemide add on to hypertonic slain on neurohormonal factors in Traumatic brain injury,A randomized single blind clinical trial

##### Public title

Evaluation of effect of furosemide add on to hypertonic slain on neurohormonal factors in Traumatic brain injury

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: All of patients with 18-90 years old with closed head trauma ; associated with brain edema confirmed with CT scan ; Hemodynamically stable before management; GCS<14; Patients with CV line ; admission with in 24 hours of initial insult

##### Age

From **18 years** old to **90 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)**

Single blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Mazandaran University of medical sciences

**Street address**

Vice chancellor of research, moalem sq.

**City**

Sari

**Postal code**

**Approval date**

2015-11-28, 1394/09/07

**Ethics committee reference number**

IR.MAZUMS.REC.94-1924

**Health conditions studied**

**1**

**Description of health condition studied**

brain injury

**ICD-10 code**

S06.0-S06-

**ICD-10 code description**

Concussion, Traumatic cerebral oedema, Diffuse brain injury, Focal brain injury, Epidural haemorrhage, Traumatic subdural haemorrhage, Traumatic subarachnoid haemorrhage, Intracranial injury with prolonged coma, Other intracranial injuries, Intracranial inju

**Primary outcomes**

**1**

**Description**

Blood Na

**Timepoint**

1,2,3,4 days

**Method of measurement**

Serum concentraion

**2**

**Description**

Blood osmolality

**Timepoint**

1,2,3,4 days

**Method of measurement**

With calculation of ions affect the osmolarity

**Secondary outcomes**

**1**

**Description**

\$100B

**Timepoint**

1,2,3,4 days

**Method of measurement**

Kit (spectrophotometry)

**2**

**Description**

NSE

**Timepoint**

1,3,5

**Method of measurement**

Kit (spectrophotometry)

**Intervention groups**

**1**

**Description**

One groups receives at a dose of 20ml / h and furosemide for 0.05mg / kg / h for 72 hours .

**Category**

Treatment - Drugs

**2**

**Description**

Control group receives for 72 hours at a dose of 20ml /h saline hyperton

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Emam khomeini hospital and educational center, Sari  
**Full name of responsible person**  
Dr. Shahram Ala  
**Street address**  
**City**  
Sari

**Fax**  
**Email**  
drmjafari1985@yahoo.com  
**Web page address**

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Mazandaran University of Medical Sciences, Vice  
chancellor for research  
**Full name of responsible person**  
Dr Ahmadali Enayati  
**Street address**  
Mazandaran University of Medical Sciences, Vice  
chancellor for research, Moallem square, Sari,  
Mazandaran, Iran Sari  
**City**  
Sari

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Mazandaran University of Medical Sciences, Vice  
chancellor for research

### 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**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Dr.Marziyeh Jafari  
**Position**  
Clinical pharmacy student  
**Other areas of specialty/work**  
**Street address**  
Payambar azam university complex, Mazandaran  
University of Medical Sciences, Faculty of  
pharmacy,18  
**City**  
Sari  
**Postal code**  
**Phone**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mazandaran university of medical sciences  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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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*