

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 osmolality

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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran university of medical sciences
Full name of responsible person
Dr. Shahram Ala
Position
Mazandaran University of Medical Sciences
Other areas of specialty/work
Street address
Payambar azam university complex, Mazandaran
University of Medical Sciences, Faculty of pharmacy,
Km 18 Khazar abad road, Sari, Mazandaran, Iran
City
Sari
Postal code
Phone
00
Fax
Email
sala@mazums.ac.ir
Web page address

Person responsible for updating data

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,
Km 18 Khazar abad road, Sari, Mazandaran, Iran
City
Sari
Postal code
Phone
00
Fax
Email
drmjafari1985@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty

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
00

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty