Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Effect of 0.5, 1, 1.5 g / kg doses of monnitol 20% in reduction of brain edema and increase in post-traumatic consciousness level in patients with diffuse axonal injury accompanied with edema and brain midline shifting more than 5 mm

Protocol summary

Summary

This study compared the effects of different doses of 0.5, 1, 1.5 g / kg of mannitol 20% inreducing brain edema and increasing alertness in post-traumatic patients with the diagnosis of diffuse axonal injury accompanied by edema and brain shifting of more than 5 mm. Patients with diffuse axonal injury aged 15 to 60 years old, level of consciousness less than 8, brain edema, brian shifting from midline greater than 5 mm and no history of renal failure or severe electrolyte imbalances. Variables of 30 patients treated by doses of 0.5, 1 and 1.5 g/kgwere measured every 6 hours for 48 hours and brain edema, shifting from midline and level of consciousness in patients were evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013040312888N1**
Registration date: **2013-06-20, 1392/03/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-06-20, 1392/03/30

Registrant information

Name

Mohammad Asghari

Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Science

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2013-03-15, 1391/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of 0.5, 1, 1.5 g / kg doses of monnitol 20% in reduction of brain edema and increase in post-traumatic consciousness level in patients with diffuse axonal injury accompanied with edema and brain midline shifting more than 5 mm

Public title

The effect of mannitol in reducing brain edema and increasing the level of consciousness in patients with brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

(Inclusion criteria: age 15 to 60 years, patients with diffuse axonal injury: level of consciousness of less than 8; edema and brian shifting from midline of more than 5 mm; willingness to participate in the study. Exclusion

criteria: renal failure, intense electrolyte imbalance; death throughout the study)

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

Research Deputyof Faculty Medicine

Street address

Research Department, 3rd floor of 2nd central bulding of Tabriz university of Medical Sciences, Daneshghah Ave.

City

Tabriz

Postal code

3357310112

Approval date

2011-05-01, 1390/02/11

Ethics committee reference number

91200

Health conditions studied

1

Description of health condition studied

Diffuse brain injury

ICD-10 code

s06.2

ICD-10 code description

Diffuse brain injury

Primary outcomes

1

Description

Brain edema severity

Timepoint

On admission and 48 hours after admission

Method of measurement

Brain edema will be meseaured by CT scan on admission and 48 hours after admission and the findings will be graded based on the cistern basal being open, semi-open and close from1-3.

Secondary outcomes

1

Description

Brain midline shift

Timepoint

On admission and 48 hours after admission

Method of measurement

Brain edema will be meseaured by CT scan on admission and 48 hours after admission and will be calculated based on the midline shifting formula.(middle shift=biparietal diametr-2SP)

2

Description

level of consciousness

Timepoint

On admission and 48 hours after admission

Method of measurement

The GCS Glasgow Coma Scale score of 3 to 15 have been measured to be between

Intervention groups

1

Description

mannitol 20% 0.5 mg/kg WB

Category

Treatment - Drugs

2

Description

Mannitol%20 1g/kg WB

Category

Treatment - Drugs

3

Description

mannitol%20 1.5g/kg WB

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Educational and Training Hospital
Full name of responsible person
Hadi Ebrahimi
Street address
Emam Reza Hospital, Golgasht St
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Asgari Mohammad
Street address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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

Person responsible for scientific inquiries

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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