Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Efficacy of Magnesium Sulfate on the Clinical Course and GCS of Patients with Severe Diffuse Axonal Injury

Protocol summary

Summary

The present study was conducted to evaluate magnesium sulfate therapeutic efficacy and safety in patients with a severe diffuse axonal injury . 38 Traumatic patients diagnosed with severe and moderate diffuse axonal injury at the age of 18 to 65 years old who were admitted within 1 hour after trauma enrolled in our study.All patients randomly assigned to 1 of 2 treatment groups. group A: the patients were given an initial loading dose of 50 mg/kg magnesium sulfate and then 50 mg/kg every 6 hours up to 24 hours after the trauma and group B: given normal saline as a plasebo.The initial treatment consisted of ventilation, antibiotic prophylaxis with cefotaxime or ceftriaxone, seizure prophylaxis with phenytoin, gastric ulcer prophylaxis with ranitidine and urinary catheterization were done in all patents. Finally all patients were evaluated within 2 month with respect to clinical regression, GCS and motor function scores to evaluate efficacy of magnesium sulfate in the patients with diffuse axonal injury.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111158098N2**
Registration date: **2012-01-11, 1390/10/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-01-11, 1390/10/21

Registrant information

Name

Yazdan Dokht Gafari Momeneh

Name of organization / entity

faculty of medicine, tabriz medical university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy for Research,Faculty of Medicine.Tabriz University of Medical Science

Expected recruitment start date

2009-04-04, 1388/01/15

Expected recruitment end date

2011-02-04, 1389/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Magnesium Sulfate on the Clinical Course and GCS of Patients with Severe Diffuse Axonal Injury

Public title

Effect of Magnesium Sulfate on Diffuse Axonal Injury

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Older than 18 and less than 65 years old; the time gap between trauma and admission to the medical center not exceeding more than one hour
Exclusion criteria: renal failure; pregnancy; seizure; cardiac heart failure;cranial hematoma; intracranial surgery for hematoma; refractory systemic hemorrhage requiring blood product transfusion; intracranial hemorrhage

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: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Deputy for Research,Faculty of Medicine,Tabriz University of Medical Science
Street address
Deputy for Research,Faculty of Medicine, Golgasht Ave. Tabriz.IR.IRAN
City
Tabriz
Postal code
Approval date
2010-08-03, 1389/05/12
Ethics committee reference number
543488

Health conditions studied

1

Description of health condition studied
brain trauma
ICD-10 code
S06.2
ICD-10 code description
Diffuse brain injury

Primary outcomes

1

Description
Glascow coma scale (GCS)
Timepoint
with in 2 month after trauma
Method of measurement
According to GCS score table

2

Description
motot function
Timepoint
2 month after trauma
Method of measurement
according to evaluating muscle force

Secondary outcomes

1

Description
adverse effect of magnesium sulfate
Timepoint
within 24 hours after magnesium sulfate administration
Method of measurement
yes or no

Intervention groups

1

Description
initial intravenous loading dose of 50mg/kg magnesium sulfate within one hour after trauma and then 50mg/kg every 6 hour magnesium sulfate up to 24 hours after trauma
Category
Treatment - Drugs

2

Description
intravenous normal saline with the same dose of drug intervention
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy for Research,Faculty of Medicine.Tabriz University of Medical Science

Full name of responsible person

DR. A. Meshkini

Street address

Deputy for Research,Faculty of Medicine, Golgasht Ave. Tabriz.IR.IRAN

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy for Research,Faculty of Medicine.Tabriz University of Medical Science

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

Tabriz University of Medical Science

Full name of responsible person

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Position

Medical Student

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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