Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of magnesium sulfate infusion with placebo on prevention of brain injury in craniotomy surgery patients

Protocol summary

Summary

In this study effect of treatment with Magnesium as a neuroprotective agent in brain surgery would be evaluated. In this double blind, placebo controlled, randomized clinical trial study a group of 60 craniotomy surgery patients admitted to Sina Hospital neurosurgery ward will participate. Patients with renal insufficiency, heart failure or any contraindications for magnesium or previous magnesium intake would be excluded. Patients will be randomly assigned to control and intervention groups each consisted of 30 patients. Intervention group will receive 5 grams of magnesium sulfate equal to 525 milligrams of elemental magnesium in 1 liter of saline solution over 6 hours infusion daily for 2 day before and during craniotomy surgery. Control group will receive normal saline as placebo in same manner. Anti-inflammatory factor CRP and S100B protein will be measured as brain injury factors before intervention with drug or placebo then at the beginning and 24 hours after Craniotomy surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204159475N1**
Registration date: **2013-07-16, 1392/04/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-16, 1392/04/25

Registrant information

Name

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Name of organization / entity

Shahid Beheshti University of Medical Sciences, Faculty of Pharmacy

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Recruitment status

Recruitment complete

Funding source

vise-challenger of research, Tehran University of Medical Sciences.

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of magnesium sulfate infusion with placebo on prevention of brain injury in craniotomy surgery patients

Public title

Evaluation of Magnesium effects on brain tumor surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: eligible patients for brain tumor craniotomy exclusion criteria of the study: - creatinine greater than 1.5 mg / dl - Renal failure and nephrotic syndrome - Heart rate below 60 beats per minute - Severe metabolic disorders - Coagulation disorders (coagulopathy) - Myasthenia Gravis - Previous use of

magnesium - Diabetes Mellitus - Age over 60 or under 18 - GCS score less than 6 - Major cardiopulmonary disease

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Tehran University of Medical Sciences

Street address

6th floor, Tehran University of Medical Sciences central building, Keshavarz Boulevard

City

Tehran

Postal code

Approval date

2012-12-03, 1391/09/13

Ethics committee reference number

2132/130/91/د

Health conditions studied

1

Description of health condition studied

neoplasm of brain

ICD-10 code

C71.9

ICD-10 code description

Malignant neoplasm of brain (unspecified)

Primary outcomes

1

Description

CRP

Timepoint

before intervention, before surgery, after surgery

Method of measurement

ELISA kit

2

Description

S100b protein

Timepoint

before intervention, before surgery, after surgery

Method of measurement

ELISA kit

Secondary outcomes

1

Description

Neurological adverse reactions

Timepoint

After surgery up to 6 month

Method of measurement

Clinical evaluation by neurosurgeon or neurologist

2

Description

Pain and bleeding during and after surgery

Timepoint

During and after surgery

Method of measurement

Clinical evaluation by anesthesiologist

Intervention groups

1

Description

5 grams of magnesium sulfate in 1 liter of normal saline via intravenous infusion over 6 hours daily for 2 days before surgery and 5 grams of magnesium sulfate in 1 liter of normal saline via intravenous infusion over 6 hours during surgery

Category

Treatment - Drugs

2

Description

Infusion of 1 liter of normal saline over 6 hours daily for 2 days before surgery and infusion of 1 liter of normal saline over 6 hours during surgery

Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurosurgery ward of Sina Hospital
Full name of responsible person
Abbas Amir Jamshidi
Street address
Sina Hospital, Emam Khomeini Square.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vise-Challenger of research of Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
Central Building of University, Ghods Avenue, Keshavarz Boulevard
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vise-Challenger of research of Tehran 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
Name of organization / entity
Sina Hospital
Full name of responsible person
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Person responsible for updating data

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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