Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparing effect of magnesium sulfate and normal saline on intraoperative hemodynamic of patients undergoing cerebral aneurism surgery and rate of postoperative cerebral vasospasm

Protocol summary

Summary

Objective: Effect of magnesium sulfate on intraoperative hemodynamic undergoing cerebral aneurism surgery and rate of postoperative cerebral vasospasm. Design: Interventional, Randomized, Single blind (researchers were not aware), Target sample size : 46 People. Setting and conduct: The magnesium group received magnesium sulfate 50% (20 mg/per kg) (manufactured by Pasteur Institute of Iran), diluted in 100 cc normal saline over 15 min before anesthetic induction. Then, 10 mg/kg/h of magnesium sulfate with saline solution is infused within fifteen minutes for the patients after clip application. If the mean arterial pressure decreases to less than 80 mmHg, propofol infusion, fentanyl, and magnesium sulfate are reduced or stopped to maintain the arterial pressure in 80-100 mmHg range, before clip application. In the normal saline group, the same volume of magnesium sulfate is administered to the patients. Intraoperative fluid management is performed according to the standard procedures (4-2-1 rule); bleeding is compensated by a three-fold increase in magnesium and 0.9% normal saline. Participants including major inclusion criteria: candidate for brain aneurysm surgery after 3 days of aneurysm bleeding; American Society of Anesthesiologists (ASA) class I and II. Participants including major exclusion criteria: pathology of cardiovascular system; heart failure [Ejection fraction (EF) less than 40%], Previous history of hypertension; Liver or kidney diseases (impaired Liver function test (FT) and Glomerular filtration rate (GFR) less than 50 ml/min); Motor, neurological, and muscle disorders, coagulopathy [Prothrombin time (PT) more than 16, International Normalized Ratio (INR) more than 1.5; Partial thromboplastin time (PTT) more than 35]; Hypomagnesaemia, More than 60 years of age; History of allergy to any of the used medications in the experiment, Overweight [Body mass index (BMI) more than 30]; Previous use of calcium channel blockers; Atrioventricular block. Intervention group: Magnesium sulphate 50%, 20 mg/kg, during 15 minutes before infusion of anesthesia and 10 mg/kg/hour till 15 minutes after end of improvising the tresses. Control group: Normal Saline 0.9%, Fluid therapy During surgery according to standard procedures (Rule 4-2-1) and compensation bleeding occurs with three times of Normal Saline 0.9%. Primary outcome measure: Vasospasm after intervention, Daily, By angiography and transcranial Doppler

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013042813159N1**
Registration date: **2014-06-14, 1393/03/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-06-14, 1393/03/24

Registrant information

Name

Shima Sheybani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Mashhad University of Medical Sciences

Expected recruitment start date
2014-05-25, 1393/03/04
Expected recruitment end date
2015-05-25, 1394/03/04
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing effect of magnesium sulfate and normal saline on intraoperative hemodynamic of patients undergoing cerebral aneurism surgery and rate of postoperative cerebral vasospasm

Public title
Evaluation of effect of magnesium sulfate on reduction of cerebral vasospasm
Purpose
Treatment
Inclusion/Exclusion criteria
The major inclusion criteria: candidate for brain aneurysm surgery after 3 days of aneurysm bleeding; American Society of Anesthesiologists (ASA) class I and II. The major exclusion criteria: pathology of cardiovascular system; heart failure [Ejection fraction (EF) less than 40%]. Previous history of hypertension; Liver or kidney diseases (impaired Liver function test (FT) and Glomerular filtration rate (GFR) less than 50 ml/min); Motor, neurological, and muscle disorders, coagulopathy [Prothrombin time (PT) more than 16, International Normalized Ratio (INR) more than 1.5; Partial thromboplastin time (PTT) more than 35]; Hypomagnesaemia, More than 60 years of age; History of allergy to any of the used medications in the experiment, Overweight [Body mass index (BMI) more than 30]; Previous use of calcium channel blockers; Atrioventricular block.
Age
From **20 years** old to **61 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Patients using a randomized block split into two groups of 23 people magnesium sulphate and normal saline. Researchers are unaware.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street, Mashhad
City
Mashhad
Postal code
Approval date
2013-11-16, 1392/08/25
Ethics committee reference number
920552

Health conditions studied

1

Description of health condition studied
Cerebral aneurism
ICD-10 code
160.7
ICD-10 code description
Subarachnoid haemorrhage from intracranial artery, unspecified

Primary outcomes

1

Description
Vasospasm
Timepoint
After intervention, daily
Method of measurement
Angiography and transcranial Doppler

2

Description
Mean arterial pressure
Timepoint
Before infusion, 5 minutes after infusion, every 15 minutes after infusion
Method of measurement
Arterial Line during the surgery

3

Description
Heart rate
Timepoint
Before infusion, 5 minutes after infusion, every 15 minutes after infusion
Method of measurement
Heart monitoring during the surgery

Secondary outcomes

1

Description
Bleeding rate
Timepoint
End of surgery
Method of measurement
Based on CC of gases and suction contents

2

Description
The amount of anesthetic drugs used (propofol 2 mg/kg, fentanyl 2 mcg/kg, atracurium 0.5 mg/kg lidocaine 1.5 mg/kg)
Timepoint
End of surgery
Method of measurement
Based on patient weight (kg) and Duration of Surgery

Intervention groups

1

Description
Intervention group: Magnesium sulphate 50%, 20 mg/kg diluted in 100 ml of saline normal, manufactured by Pasteur Institute of Iran, during 15 minutes before infusion of anesthesia and 10 mg/kg/hour till 15 minutes after end of improvising the tresses
Category
Treatment - Drugs

2

Description
Control group: Normal Saline 0.9%, Fluid therapy During surgery according to standard procedures (Rule 4-2-1) and compensation bleeding occurs with three times of Normal Saline 0.9%
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Shima Sheybani
Street address
Anesthesia group, Ghaem Hospital, Mashhad
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Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street, Mashhad
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Mashhad 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
Ghaem Hospital
Full name of responsible person
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Person responsible for scientific inquiries

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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