Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison effects of magnesium sulfate and placebo in prevention of shivering during spinal anesthesia in cesarean section

Protocol summary

Summary

Purpose: This study is prospective, randomized, double-blinded and clinical trial. 80 patients candidate for spinal anesthesia in cesarean section were chosen and divided randomly to same groups. Method and intervention: Patients were randomly assigned into two groups. The first group of patients is received Magnesium sulfate and group two is received normal saline as placebo. Immediately start inject drug after spinal anesthesia, the first group of patients is received 30mg/kg Magnesium sulfate (The maximum dose is 4 gr of magnesium infusion) We dilute it in 50 cc normal saline and infuse at 30 minutes and in group two (control group) infuse 50 cc normal saline as placeb, the surgeon and patients are bline about the type of drug. Inclusion/exclusion criteria: Inclusion criteria: caesarean section under spinal anesthesia in a Pregnant women with ASA I exclusion criteria: ASAII and above; Fever before surgery(T>38) and Hypothermia(T<36.5); Absolute prohibition for spinal anesthesia; Allergy to case study drugs; Thyroid Disease; Parkinson; Raynaud's syndrome; Ischemic heart disease; cerebrovascular disorders; Intraoperative blood transfusion; time of surgery more than 120 minutes; administration of Magnesium; administration of of pethidine; Hypertension; renal disease; history of use of cardiac and Hypertension drug. Primary and Secondary outcome: shiver,temperature. Secondary outcome: Blood pressure, Heart rate, Nausea & Vomiting. Control group: received 50cc Normal saline. Intervention group: received 30mg/kg so4 that dilute in 50cc Normal saline.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308254780N4**
Registration date: **2013-09-05, 1392/06/14**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-09-05, 1392/06/14

Registrant information

Name
Mohammad Alipour
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad Univercity of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effects of magnesium sulfate and placebo in prevention of shivering during spinal anesthesia in cesarean section

Public title

Effects of magnesium sulfate in prevention of shivering during spinal anesthesia in cesarean section

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: caesarean section under spinal anesthesia in a Pregnant women with ASA I. Exclusion criteria: ASAII and above; Fever before surgery(T>38) and Hypothermia(T<36.5); Absolute prohibition for spinal anesthesia; Allergy to case study drugs; Thyroid Disease; Parkinson; Raynaud's syndrome; Ischemic heart disease; cerebrovascular disorders; Intraoperative blood transfusion; time of surgery more than 120 minutes; administration of Magnesium; administration of of pethidine; Hypertension; renal disease; history of use of cardiac and Hypertension drug.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
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
Ethics Committee of Mashhad University of Medical Sciences
Street address
Vice Chancellor for Research, Mashhad University of Medical Science, Ghoreishi apartment, Daneshgah street
City
Mashhad
Postal code
Approval date
2012-10-13, 1391/07/22
Ethics committee reference number
910049

Health conditions studied

1

Description of health condition studied
Spinal anesthesia
ICD-10 code
O29.5
ICD-10 code description
Other complications of spinal and epidural anaesthesia during pregnancy

Primary outcomes

1

Description
shiver
Timepoint
During opreation every 15 minutes to 120 minutes
Method of measurement
Rate of Crossely & Mahajan

2

Description
Temperature
Timepoint
Befor spinal anesthesia and every 15 minutes to 120 minutes during surgery
Method of measurement
Genius 2 Electronic Thermometer

Secondary outcomes

1

Description
Blood pressure
Timepoint
Every 15 minutes to 120 minutes during surgery
Method of measurement
Non-invasive with Cuff

2

Description
Heart rate
Timepoint
Every 15 minutes to 120 minutes during surgery
Method of measurement
monitoring

3

Description
Nausea & Vomiting
Timepoint
Every 15 minutes to 120 minutes during surgery
Method of measurement
Observation and question

Intervention groups

1

Description
Intervention group: received 30mg/kg Magnesium sulfate (dilute it in 50 cc normal saline)
Category
Treatment - Drugs

2

Description
Control group: received 50 cc of normal saline
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Dr Mohammad Alipour
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Mashhad University of Medical Science
Full name of responsible person
Dr Tavakol Afshar
Street address
Vice Chancellor for Research, Mashhad University of Medical Science, Ghoreishi apartment, Daneshgah street
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 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
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Person responsible for updating data

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Web page address

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