Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the effect of different dose of interatechal magnesium sulfate on quality of sensory-motor block in elective cesarean section

Protocol summary

Summary

The aim of this double-blinded randomized clinical trial was evaluation the efficacy of different dose of interatechal magnesium sulfate on quality of sensory-motor block in elective cesarean section. A total of 132 ASA physical status I-II women undergoing elective cesarean section with spinal anesthesia were randomized to four groups: 1- 2.5 cc Bupivacaine 0.5%+ 0.2cc Normal Saline; 2- 2.5 cc Bupivacaine 0.5%+ 0.1 cc Normal Saline+ 0.1 cc Magnesium sulfate 50%; 3 -2.5 cc Bupivacaine 0.5%+ 0.05 cc Normal Saline+ 0.15 cc Magnesium sulfate 50%; 4- 2.5 cc Bupivacaine 0.5%+ 0.2 cc Magnesium sulfate 50%. All parturients received 10 ml/kg ringer lactate solution. Then spinal anesthesia was done in sitting position using 25 G sprotte needle. Participants were including parturients with ASA physical status I-II, scheduled for elective cesarean section, under spinal anesthesia and excluded with suspicious to bleeding disturbances, atopia, diabetes mellitus, existence of liver or kidney diseases, drugs abuse, hypertension of pregnancy, preeclampsia. Sensory and motor onset time, duration of sensory and motor block compared among the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107112405N8**
Registration date: **2011-11-05, 1390/08/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-11-05, 1390/08/14

Registrant information

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Recruitment status

Recruitment complete

Funding source
Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-07-23, 1390/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of different dose of interatechal magnesium sulfate on quality of sensory-motor block in elective cesarean section

Public title

The effect of interatechal magnesium sulfate on the quality of block in elective cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Parturients; ASA physical status I-II; scheduled for elective cesarean section; under spinal anesthesia; Exclusion Criteria: suspicious to bleeding

disturbances; atopia; diabetes mellitus; existence of liver or kidney diseases; drugs abuse; hypertension of pregnancy; preeclampsia

Age
From **15 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **132**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice-chancellor for Research, Ethics committee of Isfahan University of Medical Sciences

Street address
Vice-chancellor for Research, Isfahan University of Medical Sciences

City
Isfahan

Postal code

Approval date
2010-04-20, 1389/01/31

Ethics committee reference number
389483

Health conditions studied

1

Description of health condition studied
Complications of anesthesia during pregnancy

ICD-10 code
O29.8

ICD-10 code description
Other complications of anesthesia during pregnancy

Primary outcomes

1

Description
Sensory block onset time

Timepoint
time from intratechal injection to T6 dermatomal level

Method of measurement
pin prick test with needle

2

Description
motor block onset time

Timepoint
time from intratechal injection to ankle flexion

Method of measurement
ask to parturient for flexion of ankle- measure with watch in minute

3

Description
Duration of motor block

Timepoint
time from intrathecal injection to ability of ankle flexion

Method of measurement
with watch in minute

4

Description
Duration of sensory block

Timepoint
time from intrathecal injection to presence of pain

Method of measurement
with watch in minute

Secondary outcomes

1

Description
Pain intensity

Timepoint
recovery room(0) ,0.5 , 1, 1.5, 2, 2.5, 3, 3.5 and 4 hours postoperative

Method of measurement
Visual Analogous Scale (VAS) and scoring from 0 to 10

Intervention groups

1

Description
2.5 cc Bupivacaine 0.5%+ 0.2cc Normal Saline. Duration of intervention: single dose in 10 seconds spinal injection. Duration of treatment: During spinal anesthesia in operating room

Category
Treatment - Drugs

2

Description
2.5 cc Bupivacaine 0.5%+ 0.1 cc Normal Saline+ 0.1 cc Magnesium sulfate 50%. Duration of intervention: single dose in 10 seconds spinal injection. Duration of treatment: During spinal anesthesia in operating room
Category
Treatment - Drugs

3

Description
2.5 cc Bupivacaine 0.5%+ 0.05 cc Normal Saline+ 0.15 cc Magnesium sulfate 50%. Duration of intervention: single dose in 10 seconds spinal injection. Duration of treatment: During spinal anesthesia in operating room
Category
Treatment - Drugs

4

Description
2.5 cc Bupivacaine 0.5%+ 0.2 cc Magnesium sulfate 50. Duration of intervention: single dose in 10 seconds spinal injection. Duration of treatment: During spinal anesthesia in operating room
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Medical Center
Full name of responsible person
Dr. Mitra Jabalameli
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences
Full name of responsible person
Dr. Payman Adibi
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Vice-chancellor for Research, Isfahan University of Medical Sciences, Hezar Jarib St.
City
Isfahan
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, Isfahan 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
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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