

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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

Name

Mitra Jabalameli

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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+98 31 1668 7472

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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

Street address

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

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mitra Jabalameli

Position

Specialist and Associate professor of Anesthesia and intensive care

Other areas of specialty/work

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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