Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The evaluation of the effect of adding Magnesium Sulfate to intrathecal Marcain to control shivering during cesarean section surgery with spinal anesthesia

Protocol summary

Summary

This study is aimed to evaluate the effect of adding MgSO4 to intrathecal marcain to control shivering during cesarean section surgery with spinal anesthesia. Sixty patients, ASA physical status I or II, aged between 18 - 35 years, undergoing cesarean surgery in Rasoul Hospital during 2010 to 2011, are included in this randomized, prospective, double-blind and placebo-controlled study. Patients are randomized into two groups of 30 individuals. The control group receives normal saline and treatment group receives magnesium sulfate. The treatment group receives 2 cc of marcain 0.5% (10 mg) and 0.5 cc of magnesium sulfate 5% (25 mg) and control group receives 2 cc of marcain 0.5% and 0.5 cc of normal saline. Body temperature will be recorded before spinal block, immediately after spinal block and each 30 mine during 1 hour after admission to recovery. Indeed, vital sign, 5 minutes for 15 minutes then each 10 minutes till the end of recovery will be recorded. Sedation will be recorded, before spinal block, immediately after spinal block, each 30 minutes during 1 hour after admission to recovery. Shivering will be recorded during 90 minutes after spinal block in 0, 5, 10, 15, 20, 30, 40, 50, 60 and 90 minutes by physician who is unaware of the type of treatment given to the patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101055182N4**
Registration date: **2011-02-02, 1389/11/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-02-02, 1389/11/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences and Health Services

Expected recruitment start date

2011-01-21, 1389/11/01

Expected recruitment end date

2012-01-21, 1390/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effect of adding Magnesium Sulfate to intrathecal Marcain to control shivering during cesarean section surgery with spinal anesthesia

Public title

The evaluation of the effect of adding Magnesium Sulfate to intrathecal Marcain to control shivering during

cesarean section surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ASA physical status I or II, age 18-35 years old, signing consent to participate in the study. Exclusion criteria: Patients not willing participate in project, pre-eclampsia, lidocaine and magnesium sulfate allergy, drug and alcohol abuse, neuropathy, infection in block site, respiratory distress, coagulopathy.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

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 and Health Services

Street address

Poorsina Ave.

City

Tehran

Postal code

Approval date

2010-08-01, 1389/05/10

Ethics committee reference number

890.1

Health conditions studied

1

Description of health condition studied

Shivering during cesarean section surgery

ICD-10 code

T88.5

ICD-10 code description

Hypothermia following anesthesia

Primary outcomes

1

Description

Shivering

Timepoint

During 90 minutes after spinal block in 0, 5,10,15,20,30,40,50,60 and 90 minutes

Method of measurement

None, Mild, Moderate, Severe

Secondary outcomes

1

Description

Central body temperature

Timepoint

Before spinal block, immediately after spinal block, each 30 mine during 1 hour after admission to recovery

Method of measurement

Thermometer

2

Description

Systolic arterial pressure

Timepoint

5 minutes for 15 minutes then each 10 minutes til the end of recovery

Method of measurement

Sphygmomanometer

3

Description

Heart rate

Timepoint

5 minutes for 15 minutes then each 10 minutes til the end of recovery

Method of measurement

Rate/min

4

Description

Sedation

Timepoint

Before spinal block, immediately after spinal block, each 30 minutes during 1 hour after admission to recovery

Method of measurement

Basd on Ramsy criteria

Intervention groups

1

Description
The magnesium sulfate group receive 2 cc marcain 0.5% (10 mg), 0.5 cc magnesium sulfate 5% (25 mg)
Category
Treatment - Drugs

2

Description
The control group receive 2 cc marcain 0.5% , 0.5 cc normal saline
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Hospital
Full name of responsible person
Seyed Hamid Reza Feiz
Street address
Poorsina Ave.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences and Health Services
Full name of responsible person
Hamid Reza Feiz, MD
Street address
Poorsina Ave.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences and Health Services
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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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