# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 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**

**Name**
Hamid Reza Faiz
**Name of organization / entity**
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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.
**City**
Tehran
**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**
**Name of organization / entity**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*