

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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 MgSO<sub>4</sub> 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

Tehran University of Medical Sciences and Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4481 9954

###### Email address

h.faiz@iums.ac.ir

##### 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

Tehran University of Medical Sciences and Health Services

#### Full name of responsible person

Hamid Reza Feiz MD

#### Position

Anesthesiologist/ Assistant Professor

#### Other areas of specialty/work

#### Street address

Poorsina Ave.

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+98 21 4481 9954

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#### Email

h.faiz@iums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Rasoul Hospital

#### Full name of responsible person

Hamid Reza Feiz MD

#### Position

Anesthesiologist

#### Other areas of specialty/work

#### Street address

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#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences and Health Services

#### Full name of responsible person

Hamid Reza Faiz

#### Position

Anesthesiologist, Assistant professor

#### Other areas of specialty/work

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**Email**

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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*