

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison effects of magnesium sulfate and placebo in prevention of shivering during spinal anesthesia in cesarean section

#### Protocol summary

##### Summary

Purpose: This study is prospective, randomized, double-blinded and clinical trial. 80 patients candidate for spinal anesthesia in cesarean section were chosen and divided randomly to same groups. Method and intervention: Patients were randomly assigned into two groups. The first group of patients is received Magnesium sulfate and group two is received normal saline as placebo. Immediately start inject drug after spinal anesthesia, the first group of patients is received 30mg/kg Magnesium sulfate (The maximum dose is 4 gr of magnesium infusion) We dilute it in 50 cc normal saline and infuse at 30 minutes and in group two (control group) infuse 50 cc normal saline as placebo, the surgeon and patients are blind about the type of drug. Inclusion/exclusion criteria: Inclusion criteria: caesarean section under spinal anesthesia in a Pregnant women with ASA I exclusion criteria: ASAII and above; Fever before surgery( $T > 38$ ) and Hypothermia( $T < 36.5$ ); Absolute prohibition for spinal anesthesia; Allergy to case study drugs; Thyroid Disease; Parkinson; Raynaud's syndrome; Ischemic heart disease; cerebrovascular disorders; Intraoperative blood transfusion; time of surgery more than 120 minutes; administration of Magnesium; administration of pethidine; Hypertension; renal disease; history of use of cardiac and Hypertension drug. Primary and Secondary outcome: shiver, temperature. Secondary outcome: Blood pressure, Heart rate, Nausea & Vomiting. Control group: received 50cc Normal saline. Intervention group: received 30mg/kg so<sub>4</sub> that dilute in 50cc Normal saline.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201308254780N4**

Registration date: **2013-09-05, 1392/06/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-09-05, 1392/06/14

##### Registrant information

###### Name

Mohammad Alipour

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 1801 2612

###### Email address

alipourm@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

##### Expected recruitment start date

2012-11-21, 1391/09/01

##### Expected recruitment end date

2013-04-21, 1392/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison effects of magnesium sulfate and placebo in prevention of shivering during spinal anesthesia in cesarean section

##### Public title

Effects of magnesium sulfate in prevention of shivering during spinal anesthesia in cesarean section

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: caesarean section under spinal anesthesia in a Pregnant women with ASA I. Exclusion criteria: ASAII and above; Fever before surgery( $T > 38$ ) and Hypothermia( $T < 36.5$ ); Absolute prohibition for spinal anesthesia; Allergy to case study drugs; Thyroid Disease; Parkinson; Raynaud's syndrome; Ischemic heart disease; cerebrovascular disorders; Intraoperative blood transfusion; time of surgery more than 120 minutes; administration of Magnesium; administration of pethidine; Hypertension; renal disease; history of use of cardiac and Hypertension drug.

## Age

From **18 years** old to **40 years** old

## Gender

Female

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## 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

Ethics Committee of Mashhad University of Medical Sciences

##### Street address

Vice Chancellor for Research, Mashhad University of Medical Science, Ghoreishi apartment, Daneshgah street

##### City

Mashhad

##### Postal code

#### Approval date

2012-10-13, 1391/07/22

#### Ethics committee reference number

910049

## Health conditions studied

### 1

#### Description of health condition studied

Spinal anesthesia

#### ICD-10 code

O29.5

#### ICD-10 code description

Other complications of spinal and epidural anaesthesia during pregnancy

## Primary outcomes

### 1

#### Description

shiver

#### Timepoint

During operation every 15 minutes to 120 minutes

#### Method of measurement

Rate of Crossely & Mahajan

### 2

#### Description

Temperature

#### Timepoint

Befor spinal anesthesia and every 15 minutes to 120 minutes during surgery

#### Method of measurement

Genius 2 Electronic Thermometer

## Secondary outcomes

### 1

#### Description

Blood pressure

#### Timepoint

Every 15 minutes to 120 minutes during surgery

#### Method of measurement

Non-invasive with Cuff

### 2

#### Description

Heart rate

#### Timepoint

Every 15 minutes to 120 minutes during surgery

#### Method of measurement

monitoring

### 3

#### Description

Nausea & Vomiting

#### Timepoint

Every 15 minutes to 120 minutes during surgery

#### Method of measurement

Observation and question

## Intervention groups

1

### Description

Intervention group: received 30mg/kg Magnesium sulfate ( dilute it in 50 cc normal saline)

### Category

Treatment - Drugs

2

### Description

Control group: received 50 cc of normal saline

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Ghaem Hospital

#### Full name of responsible person

Dr Mohammad Alipour

#### Street address

#### City

Mashhad

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Science

#### Full name of responsible person

Dr Tavakol Afshar

#### Street address

Vice Chancellor for Research, Mashhad University of Medical Science, Ghoreishi apartment, Daneshgah street

#### City

Mashhad

### 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, Mashhad University of Medical Science

### 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

Mashhad University of Medical Sciences

#### Full name of responsible person

Dr Mohammad Alipour

#### Position

Anesthesiologist

#### Other areas of specialty/work

#### Street address

Ghaem Hospital

#### City

Mashhad

#### Postal code

#### Phone

+98 51 1801 2612

#### Fax

#### Email

Alipourm@mums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University Of Medical Sciences

#### Full name of responsible person

Dr Mohammad Alipour

#### Position

Anesthesiologist

#### Other areas of specialty/work

#### Street address

Ghaem hospital

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#### Email

Alipourm@mums.ac.ir

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Cardiac Anesthesia Research Center, Mashhad University of Medical Sciences

#### Full name of responsible person

Dr Mohammad Alipour

#### Position

Anesthesiologist

#### Other areas of specialty/work

#### Street address

Ghaem hospital

**City**

Mashhad

**Postal code****Phone**

+98 51 1801 2612

**Fax****Email**

Alipourm@mums.ac.ir

**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*