

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Clinical trial Comparison effects of magnesium sulfate and granisetron on prevention of shivering during spinal anesthesia in cesarean section

Protocol summary

Summary

Purpose: Clinical trial Comparison effects of magnesium sulfate and granisetron on prevention of shivering during spinal anesthesia in cesarean section. A total of 80 pregnant women with ASA class I undergoing elective cesarean section to be chosen and a double blind randomized using a random number table is divided into two groups. The first group of patients magnesium sulfate received (Mg, n = 40) and patients in the group 2 (Group G, n = 40) received granisetron. After spinal anesthesia immediately began injecting drugs, the 30 mg / kg magnesium sulfate and dilute the volume of 50cc raised and within 30 minutes we were by syringe infusion pump, the maximum dose was 4 grams of magnesium infusion to consider. The other group granisetron in a dose of 40mcg/kg in the syringe injected encoded so that neither the researchers nor the patients had knowledge of the contents of the syringe. Inclusion criteria: Pregnant women who underwent spinal anesthesia for cesarean section are ASA class I. Exclusion criteria: Patients with ASA class II and above; Sensitivity to study drugs; Thyroid disease; Parkinson; Ischemic heart disease; Reception blood intraoperative; Surgery for more than 120 minutes or less than 30 minutes; History of pethidine; use of pethidine; Hypertension; Renal disease; usage of heart and blood pressure drug. Primary outcome: shiver, the temperature of the tympanic (by Genius 2 Electronic Thermometer) used to perform spinal and every 15 minutes to 120 minutes was measured during surgery. secondary outcom: Blood pressure and heart rate using the cuff and measured noninvasively monitoring device. Intervention group 1: 30mg/kg Magnesium sulfate diluted and brought to the volume of 50cc syringe infusion pump over 30 minutes we were. Intervention group 2 : Granisetron a dose of 40mcg/kg in the syringe injected encoded so that neither the researchers nor the patients had knowledge of the contents of the syringe.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606144780N9**

Registration date: **2016-08-23, 1395/06/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-23, 1395/06/02

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

Mohammad Ali Alipour

Expected recruitment start date

2015-06-17, 1394/03/27

Expected recruitment end date

2016-01-17, 1394/10/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial Comparison effects of magnesium sulfate and granisetron on prevention of shivering during spinal anesthesia in cesarean section

Public title

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

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women who underwent spinal anesthesia for cesarean section are ASA class I.
Exclusion criteria: Patients with ASA class II and above; Sensitivity to study drugs; Thyroid disease; Parkinson; Ischemic heart disease; Reception blood intraoperative; Surgery for more than 120 minutes or less than 30 minutes; History of pethidine; use of pethidine; Hypertension; Renal disease; usage of heart and blood pressure drug.

Age

No age limit

Gender

Both

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**

Not 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

Ghoreishi apartment, Daneshgah street

City

Mashhad

Postal code**Approval date**

2015-05-27, 1394/03/06

Ethics committee reference number

IR.MUMS.fm.REC.135.55

Health conditions studied**1****Description of health condition studied**

Intra and post spinal anesthesia shivering

ICD-10 code

R68.0

ICD-10 code description

Hypothermia, not associated with low environmental temperature

Primary outcomes**1****Description**

shiver

Timepoint

Every 15 minutes to 120 minutes during surgery

Method of measurement

With Crossly and Mahjon five-point scoring system and tympanic thermometer devices

Secondary outcomes**1****Description**

Blood pressure

Timepoint

Every 15 minutes to 120 minutes during surgery

Method of measurement

Using a non-invasive cuff

2**Description**

Heart rate

Timepoint

Every 15 minutes to 120 minutes during surgery

Method of measurement

With monitoring device

Intervention groups**1****Description**

Intervention group 1: 30mg/kg Magnesium sulfate diluted and brought to the volume of 50cc syringe infusion pump over 30 minutes we were

Category

Treatment - Drugs

2**Description**

Intervention group 2 : Granisetron a dose of 40mcg/kg in the syringe injected encoded so that neither the researchers nor the patients had knowledge of the contents of the syringe.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem and Emam Reza Hospitals

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Ghoreishi apartment, Daneshgah street, Mashhad

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 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

Mashhad University of medical sciences

Full name of responsible person

Mohammad Ali Alipour

Position

Anesthesiologist

Other areas of specialty/work

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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

Mohammad Ali Alipour

Position

anesthesiologist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Mashhad University of Medical Sciences

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Ehsan Mahdavi

Position

Anesthesiologist

Other areas of specialty/work

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Mahdavia911@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