

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Different Doses of Magnesium Sulfate (30, 50, and 80 mg/kg) in Prevention of Postoperative Shivering in Patients Undergoing Spinal Anesthesia

Protocol summary

Summary

Objectives: The purpose of this study is to compare different doses of magnesium sulfate (30, 50, and 80 mg) in the prevention of postoperative shivering in patients undergoing spinal anaesthesia. **Design:** This double-blind study is a randomized clinical trial with no placebo. **Setting and conduct:** Infusion through microset 15 minutes after spinal anesthesia. **Participants:** The study population includes 99 male and female patients aged between 20-80 years old in three groups of 33 each. The main inclusion criterion was not being allergic to the prescribed medicines and the main exclusion criterion was having a central temperature less than 36.5 degrees centigrade or higher than 38 during operation. **Intervention:** The intervention includes infusing magnesium sulfate to prevent postoperative shivering after spinal anaesthesia. The treatment will be after spinal anaesthesia and the infusion will be carried out in 15 minutes. **Main outcome measures:** The primary outcome is shivering which will be measured based on the observation scale for some hours after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012432099N3**
Registration date: **2017-07-02, 1396/04/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-02, 1396/04/11

Registrant information

Name

Bahareh Ebrahimi

Name of organization / entity

Gonabad University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Deputy for Research at Gonabad University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Different Doses of Magnesium Sulfate (30, 50, and 80 mg/kg) in Prevention of Postoperative Shivering in Patients Undergoing Spinal Anesthesia

Public title

The Use of Magnesium Sulfate in Prevention of Postoperative Shivering

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: The patients must be between 20-80 years old; be willing to participate in the study; complete

the informed consent form; not have cardiac nor pulmonary diseases; not have thyroid dysfunction; not be allergic to the prescribed medicines; not suffer from Parkinson's disease; dysautonomia nor rhinod syndrome; not drink alcohol; not use vasodilator; have a central temperature of 36.5 degrees centigrade before the onset of operation; not suffer from neurologic nor psychological disorders; and have normal functioning of the kidneys and normal output of urine. Exclusion Criteria: The occurrence of any kind of clinical outcome or condition that makes the postoperative evaluation impossible; having central temperature less than 36.5 degrees centigrade or higher than 38 during operation; and requiring transfusion during surgery.

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **99**

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**

The Ethics Committee of Gonabad University of Medical Sciences

Street address

Deputy for Research at Gonabad University of Medical Sciences, Next to the Asian Road

City

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Postal code

9691793718

Approval date

2016-07-20, 1395/04/30

Ethics committee reference number

IR.GMU.REC.1395.62

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

shivering

ICD-10 code

T88.5

ICD-10 code description

Other complications of anaesthesia

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

Shivering

Timepoint

After the intervention, immediately after the infusion of magnesium sulfate, during the operation and one hour after the end of surgery

Method of measurement

Based on the observed measure

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

Blood Pressure

Timepoint

After the intervention every fifteen minutes during the operation and as long as one hour after the operation

Method of measurement

Based on mercury mm using sphygmomanometer

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

Group A will be infused once using magnesium sulfate 20% with a dose of 30 kg/mg and 100 cc volume using a microset after spinal anesthesia.

Category

Treatment - Drugs

2**Description**

Group B will be infused once using magnesium sulfate 20% with a dose of 50 kg/mg and 100 cc volume using a microset for 15 minutes after spinal anesthesia.

Category

Treatment - Drugs

3**Description**

Group C will be infused once using magnesium sulfate 20% with a dose of 80 kg/mg and 100 cc volume using a microset for 15 minutes after spinal anesthesia.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

15 khordad Bidokht Hospital

Full name of responsible person

Dr Mohsen Saheban Maleki

Street address

Bidokht

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy for Research at Gonabad University of Medical Sciences

Full name of responsible person

Dr Ali Mohamadpor

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Deputy for Research at Gonabad University of Medical Sciences, Next to the Asian Road

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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

Deputy for Research at Gonabad 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**

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Full name of responsible person

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Position

Student of Anesthesia

Other areas of specialty/work**Street address**Anaesthesia and Operating Room Department,
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Dr Mohsen Saheban Maleki

Position

Anesthesiologist, ICU Fellowship, Associate Professor

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Full name of responsible person

Mostafa Amiri

Position

Faculty Member, Assistant Professor, PhD in TEFL

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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