Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Different Ḍoses 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

Ḍeputy 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 Ḍoses 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
Gonabad

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
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Bidokht
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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
Street address
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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
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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