

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effect of prophylactic injection of magnesium sulfate versus placebo on shivering after cesarean section under spinal anesthesia: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of prophylactic injection of magnesium sulfate versus placebo on shivering after cesarean section under spinal anesthesia

Design

This is a double-blind randomized clinical trial, phase III, in which 60 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients who are candidate for cesarean referring to the Fetamieh Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of 18 to 45 years old; pregnant women; candidate for cesarean section. Exclusion criteria: body temperature above 37.5 or below 36 degree centigrade; renal or liver diseases or muscular weakness; uncontrolled thyroiditis disease; Parkinson disease; dis-autonomy; Raynaud's syndrome; cardiovascular disease; alcohol consumption; taking vasodilator medications.

Intervention groups

Intervention group: intravenous infusion of magnesium sulfate 30 mg/kg in 40 ml normal saline for 15 minutes. Control group: intravenous infusion of placebo (distilled water) in 40 ml normal saline for 15 minutes.

Main outcome variables

Primary outcome: Shivering after spinal anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N380**

Registration date: **2021-02-02, 1399/11/14**

Registration timing: **prospective**

Last update: **2021-02-02, 1399/11/14**

Update count: **0**

Registration date

2021-02-02, 1399/11/14

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-13, 1399/11/25

Expected recruitment end date

2022-02-14, 1400/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of prophylactic injection of magnesium sulfate versus placebo on shivering after cesarean section under spinal anesthesia: a double-blind randomized clinical trial	
Public title	Effect of prophylactic injection of magnesium sulfate versus placebo on shivering after cesarean section under spinal anesthesia
Purpose	Prevention
Inclusion/Exclusion criteria	
Inclusion criteria:	Age of 18 to 45 years old Pregnant women Candidate for cesarean section
Exclusion criteria:	Body temperature above 37.5 or below 36 degree centigrade Renal or liver diseases or muscular weakness Uncontrolled thyroiditis disease Parkinson disease Dis-autonomy Raynaud's syndrome Cardiovascular disease Alcohol consumption Taking vasodilator medications
Age	From 15 years old to 45 years old
Gender	Female
Phase	3
Groups that have been masked	- Participant - Outcome assessor
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
Blinding (investigator's opinion)	Double blinded
Blinding description	The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Hamadan University of Medical Sciences
Street address	Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City	Hamadan
Province	Hamadan
Postal code	6517838695
Approval date	2021-01-16, 1399/10/27
Ethics committee reference number	IR.UMSHA.REC.1399. 876
Health conditions studied	
<u>1</u>	
Description of health condition studied	Shivering
ICD-10 code	R25.1
ICD-10 code description	Tremor, unspecified
Primary outcomes	
<u>1</u>	
Description	Shivering after spinal anesthesia
Timepoint	Every 15 minutes until the end of the patient's presence in the recovery room
Method of measurement	With a clinical examination
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group: Intravenous infusion of magnesium sulfate 30 mg/kg in 40 ml normal saline for 15 minutes
Category	Treatment - Drugs

2

Description

Control group: Intravenous infusion of placebo (distilled water) in 40 ml normal saline for 15 minutes

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fetamieh Hospital in Hamadan city

Full name of responsible person

Elaheh Sharifi Asa

Street address

Fatemieh Hospital, Pasdaran Ave.

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6517838695

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Elaheh Sharifi Asa

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Genetics

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Person responsible for scientific inquiries

Contact

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Position

Anesthesiologist

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

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Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available