

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparison of Effect of Magnesium Sulfate and ondansetron in Prevention of Shivering in Patients during Spinal Anesthesia

Protocol summary

Study aim

Comparison of Effect of Magnesium Sulfate and ondansetron in Prevention of Shivering in Patients during Spinal Anesthesia

Design

The clinical trial has a control group, with parallel groups, a blind, randomized, Phase 2 on 80 patients. To randomize the 80 cards in two different colors, 40 red cards and 40 blue cards were poured into the Ondansetron group and magnesium sulfate inside the bag and were accidentally drawn up by the anesthesia technician, for each patient, a card was pulled

Settings and conduct

Pregnant women with American Society of Anesthesia class I under cesarean section with spinal procedure were studied in Amiroloemenin Hospital of Semnan and randomly compared to Ondansetron and sulfat Magnesium Effect for shivering prevention

Participants/Inclusion and exclusion criteria

conditions for entering the study pregnant women with American Society of Anesthesia class I who have a cesarean section with spinal anesthesia conditions for not entering the study pregnant women with American Society of Anesthesia class II , III , IV Fever (Central body temperature over 38 Celsius) or hypothermia (Central body temperatureless than 36.5 Celsius) contraindications of spinal anesthesia (Patient dissatisfaction, lack of patient cooperation, increased intracranial pressure) allergy to the drugs studied receiving blood during surgery History of petidine and magnesium intake before surgery

Intervention groups

In the first intervention group.30 Milligrams per kilogram diluted magnesium sulfate with 500 cc of normal saline is infused over 30 minutes by the pump syringe. The maximum dose of magnesium was 4 gram.In the second intervention group ondansetron is infused at 0.1 Milligrams per kilogram with 500 cc of normal saline for 30 minutes.

Main outcome variables

shivering, temperature, age, group therapy, blood pressure, heart rate, arterial oxygen saturation, nausea and vomiting.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171228038117N4**

Registration date: **2020-06-01, 1399/03/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-01, 1399/03/12**

Update count: **0**

Registration date

2020-06-01, 1399/03/12

Registrant information

Name

Babak Hosseinzadeh zorofchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3343 7838

Email address

babak.hoseinzadeh@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effect of Magnesium Sulfate and ondansetron in Prevention of Shivering in Patients during Spinal Anesthesia

Public title

Effect of Magnesium Sulfate and ondansetron in Prevention of Shivering in Patients during Spinal Anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

pregnant women with American Society of Anesthesia class I who have a cesarean section with spinal anesthesia

Exclusion criteria:

pregnant women with American Society of Anesthesia class II , III , IV Fever (Central body temperature over 38 Celsius) or hypothermia (Central body temperature less than 36.5 Celsius) contraindications of spinal anesthesia allergy to the drugs studied receiving blood during surgery use of petidine and magnesium before surgery

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize the study, 80 cards in two different colors, 40 red cards and 40 Blue cards was poured into a bag for the Ondansetron and Magnesium Sulfate groups, respectively, and was randomly drawn by an anesthesia technician, and a card was drawn and discarded for each patient

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients' Shivering were measured every 15 to 90 minutes by a person other than the researcher who did not know the study group and were recorded in a special form. Due to the nature of the intervention and the design of the study, only the researcher is aware of the injection. Patients will be unaware that they belong to the intervention or control group. Also, the statistician is not aware of the patients' identities and only collects

information through a numerical list that does not have the names of the patients. As a result, the study will be double-blind, and prevention will be achieved. due to differences in the treatment of patients. Also, syringes containing the drug and normal saline are identical in appearance

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Semnan University of Medical Sciences

Street address

Headquarter of Semnan University of Medical Sciences and Health Services., Basij Blvd after Amirkabir Bridge

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2020-03-14, 1398/12/24

Ethics committee reference number

IR.SEMUMS.REC.1398.301

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

Comparison of Effect of Magnesium Sulfate and ondansetron in Prevention of Shivering in Patients during Spinal Anesthesia

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

shiver

Timepoint

15 minute

Method of measurement

Crossley Mahajan criteria

Secondary outcomes

1

Description

Temperature

Timepoint

15 Minute

Method of measurement

Blood pressure device

2

Description

age

Timepoint

same time

Method of measurement

Age by year

3

Description

Heart Rate

Timepoint

15 minute

Method of measurement

monitoring

4

Description

O2 Saturation

Timepoint

15 minute

Method of measurement

pulse oxymetry

5

Description

Nausea Vomiting

Timepoint

15 minute

Method of measurement

observation

Intervention groups

1

Description

Intervention group 1:30 Milligrams per kilogram diluted magnesium sulfate 50% from Shahid Ghazi Pharmaceutical Co with 500 cc of normal saline is infused over 30 minutes by the pump syringe. The maximum dose of magnesium was 4 gram

Category

Treatment - Drugs

2

Description

Intervention group 2: ondansetron 4 miligram per 2 CC Caspian Tamin Pharmaceutical Company is infused at 0.1 Milligrams per kilogram with 500 cc of normal saline for 30 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Amirolmomenin Hospital

Full name of responsible person

babak hoseinzadeh

Street address

No. 9771., Imam Hossein Square

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babak.hoseinzadeh@semums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

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Semnan University of Medical Sciences and Health Services., Basij Boulevard,

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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

Semnan 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**

Semnan University of Medical Sciences

Full name of responsible person

babak hoseinzadeh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Elham Ghanbari

Position

Resident

Latest degree

Medical doctor

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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

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

All potential data can be shared after publication of result

When the data will become available and for how long

At the end of data collection period until the publication of results

To whom data/document is available

Only doctors and medical students

Under which criteria data/document could be used

Only when people intend to research about this topic

From where data/document is obtainable

To the scientific and executive members of the project

Email: babak.hoseinzadeh@semums.ac.ir

elhamghanbari1824@yahoo.com

What processes are involved for a request to access data/document

Communicate with the scientific and executive authorities of the project - Submitting their official letter

from research centers -using the patient's information only at designated center - Submitting their final report obtained by information

Comments