Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Amirolomenin 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 recieving 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 temperatureless than 36.5 Celsius) contraindications of spinal anesthesia allergy to the drugs studied recieving 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 Ondansteron and Magnesium Sulfate groups, respectively, and was randomly drawn by an anesthesia technician, and a card was drawn and discarded for each patien
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 Companyis 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
City
Semnan
Province
Semnan
Postal code
34731-35197
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Email
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
Street address
Semnan University of Medical Sciences and Health Services., Basij Boulevard,
City
Semnan
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Postal code
3514799442
Phone
+98 23 3344 1022
Email
info@semums.ac.ir
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 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
Other areas of specialty/work
Anesthesiology
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elhamghanbari1824@yahoo.com

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

Comments