

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Investigating the effects of magnesium sulfate compared to placebo in controlling pain during the first 24 hours after cesarean delivery with spinal anesthesia in pregnant women, a double-blind study

Protocol summary

Study aim

Determining the effects of preventive and low doses of magnesium sulfate in controlling pain and headache after cesarean section

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 118 patients. Blocked randomization will be used.

Settings and conduct

The location of the study was the postpartum ward at Al-Zahra Hospital in Rasht city. The samples of this research include pregnant women. Blinding is a two-way blind method (double blind). So that the patients will not know about the group they are assigned to. The drug will be placed in the same vials in both groups. The allocation envelope will be provided to an anesthesiologist and they are requested to prepare the drugs according to the listed group and provide them to the second anesthesiologist who will be present during the surgery. None of the people present in the operating room, including gynecologists, anesthesiologists, gynecological assistants, and nurses, will know how to allocate people.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Cesarean section with spinal anesthesia; placement in anesthesia class II; being nulliparous; acceptable candidate for cesarean section. Exclusion criteria: Magnesium intake 24 hours before surgery; History of any surgery; Suffering from kidney dysfunction; Suffering from heart dysfunction; Suffering from Lung dysfunction; Suffering from Liver dysfunction

Intervention groups

Intervention group: Patients in this group are treated with 50 mg/kg of magnesium sulfate in 100 cc of isotonic normal saline solution. Control group: Patients in this group are treated with 100 cc isotonic normal saline solution.

Main outcome variables

The amount of pain In the abdominal surgery area; Headache; the need for painkillers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090525001946N11**

Registration date: **2024-01-02, 1402/10/12**

Registration timing: **prospective**

Last update: **2024-01-02, 1402/10/12**

Update count: **0**

Registration date

2024-01-02, 1402/10/12

Registrant information

Name

Mandana Mansur Ghanaie

Name of organization / entity

Giulan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-05, 1402/10/15

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effects of magnesium sulfate compared to placebo in controlling pain during the first 24 hours after cesarean delivery with spinal anesthesia in pregnant women, a double-blind study

Public title
The effects of magnesium sulfate in controlling pain and headache in cesarean section

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Cesarean section with spinal anesthesia Placement in class II of anesthesia Being nullipara Acceptable candidate for caesarean section
Exclusion criteria:
 Magnesium intake 24 hours before surgery History of any surgery Suffering from kidney dysfunction Suffering from heart dysfunction Suffering from Lung dysfunction Suffering from Liver dysfunction Suffering from Myopathy dysfunction Suffering from neuropathy dysfunction Occurrence of severe preeclampsia symptoms Occurrence of eclampsia symptoms Having contraindications for spinal injection such as injection site infection Having contraindications for spinal injection such as coagulation disorders Severe obesity (BMI>30) Treatment with calcium receptor blocking drugs Drug addiction History of long-term use of steroids Allergy to magnesium Multiple pregnancy

Age
From **9 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **118**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked randomization method will be used. Patients are classified into two equal groups: magnesium (M) and placebo (p). For this reason, quadruple blocks will be used, which create six states: (1)MPPM. (2)MPMP. (3)MMPP. (4)PMMP. (5) PMPM. (6)PPMM . We create random integers between 0 and 60 with the help of a computer. For numbers between 0-10, we assign the first combination, for numbers 11-20, the second combination and...

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients will not know which group they are assigned to. The drug will be placed in the same vials in both groups. The allocation envelope will be provided to an anesthesiologist and They are requested to prepare the drugs according to the listed group and provide them to the second anesthesiologist who will be present during the surgery. None of the people present in the operating room, including gynecologists, anesthesiologists, gynecological assistants, and nurses, will know how to allocate people.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Research Ethics Committees of Guilan University of Medical Sciences
Street address
 Al-Zahra Hospital, Namjoo Ave.
City
 Rasht
Province
 Guilan
Postal code
 54839 -41446
Approval date
 2022-11-09, 1401/08/18
Ethics committee reference number
 IR.GUMS.REC.1401.413

Health conditions studied

1

Description of health condition studied
low and prophylactic doses magnesium sulfate on pain control

ICD-10 code
060-075

ICD-10 code description
Complications of labour and delivery

Primary outcomes

1

Description
amount of pain in the abdominal surgery area

Timepoint
In the first 6, 12, 18, and 24 hours

Method of measurement

Pain with scores between zero and ten using a Numeric Pain Rating Scale

2

Description

amount of headache

Timepoint

At 6, 12, 18, and 24 hours on the first day and at 12 o'clock on the second and third day after the operation

Method of measurement

Using the headache scoring scale (Visual Analog Scale) with scores between 0 and 10

3

Description

The amount of painkillers used

Timepoint

In the first 6, 12, 18, and 24 hours

Method of measurement

If the postoperative VAS, NRS score is greater than three

Secondary outcomes

1

Description

Sensory block

Timepoint

30 seconds before the skin incision and then from the time the skin incision is made until the end of the surgery, every five minutes until the end of the sensory block.

Method of measurement

Using a short needle (pin prick test) for sensory block

2

Description

Motor block

Timepoint

30 seconds before the skin incision and then from the time the skin incision is made until the end of the surgery, every five minutes until the end of the sensory block

Method of measurement

Evaluation of motor block based on three questions of modified Bromage scale

Intervention groups

1

Description

Intervention group: 50 mg/kg of magnesium sulfate in 100 ml of isotonic normal saline solution produced by Pasteur Institute factory and the Iran Injection and Pharmaceutical Products Company will be given intravenously as a preventive dose, once, 15 minutes before the induction of spinal anesthesia.

Category

Prevention

2

Description

Control group: they will receive 100 ml isotonic normal saline solution produced by the Iran Injection and Pharmaceutical Products Company, intravenously, as a preventive dose, once 15 minutes before the induction of spinal anesthesia.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Mandana Mansour Ghanaie

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Al-Zahra Hospital, Namjoo Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Ramzar Farzan

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Vice-chancellors for Research; front of 17-Shahrivar Hospital, Shahid Siadati street., Namjoo avenue

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No
Title of funding source
Guilan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
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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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
-
When the data will become available and for how long
-
To whom data/document is available
-
Under which criteria data/document could be used

-	data/document
From where data/document is obtainable	-
-	Comments
What processes are involved for a request to access	