Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Effect of magnesium sulfate on postoperative analgesia in woman with elective cesarian with placebo receiving group.

Protocol summary

Study aim
Determination of the effect of magnesium sulfate on post-cesarean pain control in patients referred to Amiralmomenin Hospital in Semnan from 2023 to 2024

Design
Double-blind clinical trial will be performed. Intervention and control groups of 39 people will be conducted. Using G*Power software, the final sample size was calculated 78 people.

Settings and conduct
In Amiralmomenin Hospital of Semnan, the person who gives magnesium sulfate and placebo to the patient is different from the person who collects the information, and the patient is also unaware of whether he or she receives magnesium sulfate or placebo. In the intervention group, one dose of magnesium sulfate (50 mg/kg) was injected according to the references, and in the control group, normal saline was injected.

Participants/Inclusion and exclusion criteria
Women without any special problems and underlying disease and with a history of cesarean section were referred to Amiralmomenin Hospital in Semnan in 1402 and 1403. Surgical incisions should be of Fannstein type and also have informed consent regarding the study.

Intervention groups
In the intervention group, one dose of magnesium sulfate (50 mg/kg) was injected according to the references, and in the control group, normal saline was injected.

Main outcome variables
Pain Based on VAS Score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230923059492N1**
Registration date: **2023-11-23, 1402/09/02**
Registration timing: **registered_while_recruiting**
Last update: **2023-11-23, 1402/09/02**
Update count: **0**

Registration date
2023-11-23, 1402/09/02

Registrant information

Name
Amirhossein Shahabi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3333 2064

Email address
amirshahabiahs@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2024-06-19, 1403/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of magnesium sulfate on postoperative analgesia in woman with elective cesarian with placebo receiving group.

Public title
Effect of magnesium sulfate on postoperative analgesia in woman with elective cesarian

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women who have referred to the elective cesarean section without any special problems and underlying disease and with a history of previous cesarean section have been referred for elective cesarean delivery.
Exclusion criteria:

Age
No age limit
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling by simple (or available) method from the statistical population in order to enter the center and conditional on inclusion criteria, will be selected to participate in the study and they will be divided into two equal groups of intervention and control using random permutation blocks. To prepare the random assignment list، the intervention group will be defined as a control group as B. Six permutation blocks of 4 different states A and B are numbered and considered as follows. Based on the random number table (numbers 0 to 9), each block is assigned to numbers 1 to 6 based on its number and proceeds to extract the numbers sequentially. Numbers 1 to 6 are the criteria for selecting blocks and we pass zero, 7, 8, and 9. Based on random numbers, blocks are selected successively and all four patients are assigned to either intervention or control groups based on their corresponding block.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double-blind clinical trial so that the person who gives magnesium sulfate and placebo to the patient is different from the person who collects the information and also the patient is not aware of whether they are receiving magnesium sulfate or placebo.
Placebo
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
Mostfa khomeini Ave. ; Semnan
City
Semnan
Province
Semnan
Postal code
3519734731
Approval date
2023-09-19, 1402/06/28
Ethics committee reference number
IR.SEMUMS.REC.1402.125

Health conditions studied

1

Description of health condition studied
Efficacy of magnesium sulfate in pain control after cesarean section
ICD-10 code
082.0
ICD-10 code description
عمل الكتيو سزارين

Primary outcomes

1

Description
The amount of pain within 24 hours after the operation based on vas score
Timepoint
6 _ 12 _ 18 _ 24 hours after surgery
Method of measurement
VAS score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ami al'momenin hospital, Semnan
Full name of responsible person

Sati Nik Darzi
Street address
Mostafa khomeini
City
Semnan
Province
Semnan
Postal code
111111111
Phone
+98 23 3346 0055
Email
Amir.hospital@semums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Majid mirmohammadkhani
Street address
Mostfa khomeini Ave. ; Semnan
City
Semnan
Province
Semnan
Postal code
3519734731
Phone
+98 23 3346 3052
Email
Amir.hospital@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
1
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
Sati nik darzi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Mostfa khomeini Ave. ; Semnan
City
Semnan
Province
Semnan
Postal code
3519734731
Phone
+98 23 3346 3052
Email
Sati.darzi@Gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Sati nik Darzi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Mostafa Khomeini Ave. ; Semnan
City
Semnan
Province
Semnan
Postal code
3519734731
Phone
+98 23 3346 3052
Email
Sati.darzi@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Sati nik Darzi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
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City
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Province
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Postal code
3519734731
Phone
+98 23 3346 3052
Email
sati.darzi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only a portion of the data can be shared, such as information about the main outcome or the like.
When the data will become available and for how long
Beginning of access period 6 months after publication of results
To whom data/document is available
Data will only be available to researchers working in academic and academic institutions, or people in industry can apply for it.
Under which criteria data/document could be used
There are no other conditions.
From where data/document is obtainable
Semnan University of Medical Sciences Amiralmomenin Hospital amir.hospital.@semums.ac.ir Amirhossein Shahabi amirshahabiahs@gmail.com
What processes are involved for a request to access data/document
Documents can be published as soon as the file is connected.
Comments