

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 Amirmomenin 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 Amirmomenin 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 Amirmomenin 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
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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
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Person responsible for updating data

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Email

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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