

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of adding magnesium sulfate to Marcaine intrathecal in controlling pain after cesarean section

Protocol summary

Study aim

Determination of the effect of adding magnesium sulfate to Marcaine intrathecal in post-operative cesarean section pain control

Design

Clinical trial, with control group, Draw randomization, 42 subjects, double blind

Settings and conduct

In this study, 42 pregnant women who were candidates for non-emergency cesarean section participated. Patients were randomly divided into two groups of intervention and control by lottery (n=21). This study will be conducted at Vali-e-Asr Hospital in Birjand. This study was double blinded so that the surgeon and patient and technician would not be aware of the type of used solution.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women of 15-45 years old ; no history of postoperative bleeding ; no allergy to Amide anesthetics; no history of heart, liver, renal, infectious and coagulation diseases; no history of taking psychedelic drugs and smoking. Exclusion criteria: Having neuro-muscular disease; Use of opioids or painkillers during 3 days before the study; Severe obesity (BMI \geq 35-34); Consumption of calcium channel blockers

Intervention groups

Intervention group: Patients receive 10 mg Marcaine 0.5% (CobelDarou, Tehran) and 80 mg magnesium sulfate (CobelDarou, Tehran) intrathecally (in the third and fourth or fourth and fifth intervertebral space) . Control group: Patients receive only 10 mg of intrathecal Marcaine 0.5% (CobelDarou, Tehran) intrathecally (in the third and fourth or fourth and fifth intervertebral space).

Main outcome variables

Pain, Blood pressure, Heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190123042473N1**

Registration date: **2021-02-28, 1399/12/10**

Registration timing: **retrospective**

Last update: **2021-02-28, 1399/12/10**

Update count: **0**

Registration date

2021-02-28, 1399/12/10

Registrant information

Name

Mohammad Ebnehejazi

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-05, 1396/11/16

Expected recruitment end date

2019-02-05, 1397/11/16

Actual recruitment start date

2018-02-05, 1396/11/16

Actual recruitment end date

2019-02-05, 1397/11/16

Trial completion date

2019-02-05, 1397/11/16

Scientific title

The effect of adding magnesium sulfate to Marcaine intrathecal in controlling pain after cesarean section

Public title

The effect of magnesium sulfate on post-cesarean pain control

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Women without history of bleeding after surgery. Women without allergy to Amide anesthetics. Women without history of heart, liver and renal diseases. Women without history of taking psychedelic drugs. The women with the age of 15 - 45 years. The women without history of smoking. The women without history of coagulation diseases. The women without history of infectious diseases.

Exclusion criteria:

Having neuro-muscular disease Use of opioids or painkillers during 3 days before the study Severe obesity (BMI \geq 35-34) Consumption of calcium channel blockers

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **42**

Actual sample size reached: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Lottery method; Eligible individuals were randomly assigned to one of the two groups of Marcaine intrathecal or magnesium sulfate recipients along with Marcaine intrathecal. The method of drawing was to place balls in container that the number of 1 to 9 was written inside the balls. For each patient who entered the study, a ball went out of the container accidentally. If the it was an odd number, that patient would be assigned to the Marcaine intrathecal group, and if it was even , the individual would be assigned to the magnesium sulfate receiving group, along with Marcaine intrathecal.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, two drugs of Marcaine intrathecal and magnesium sulfate recipients along with Marcaine intrathecal were prepared by a pharmacist with similar shape, color, smell, and size and placed in coded packages, and provided to the researcher. He/She prescribes them without knowing the type of each drug. Also, the person recording the patient's clinical

information and the statistical analyst will not be aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical sciences, Ghafari Ave

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2018-02-11, 1396/11/22

Ethics committee reference number

ir.bums.REC.1396.320

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

cesarean section

ICD-10 code

O75.9

ICD-10 code description

Complication of labor and delivery

Primary outcomes**1****Description**

Pain

Timepoint

at 1, 2, 3, 4, 8, 12 postoperative hours

Method of measurement

Verbal Analogue Scale method

2**Description**

blood pressure

Timepoint

at 1, 2, 3, 4, 8, 12 postoperative hours

Method of measurement

Mercury sphygmomanometer

3

Description

hear rate

Timepoint

at 1, 2, 3, 4, 8, 12 postoperative hours

Method of measurement

heart-rate monitors

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receives 10 mg of marcaine 0.5% (CobelDarou, Tehran) and 80 mg of magnesium sulfate (CobelDarou, Tehran) , intrathecally (in the third, fourth or fourth and fifth space between the vertebrae) before surgery. The severity of pain will be recorded using the VAS score and by asking the patient at 1, 2, 3, 4, and 8 hours after surgery.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group receive only 10 mg of marcaine 0.5% (CobelDarou, Tehran) intrathecally (in the third, fourth or fourth and fifth space between the vertebrae). The severity of pain will be recorded using the VAS and asking the patient at 1, 2, 3, 4, and 8 hours after surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Seyed Mohammad Ebnehejazi

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Emam Reza hospital, Taleghani Ave, Birjand, Southern Khorasan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Seyed Mohammad Ebnehejazi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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

Undecided - It is not yet known if there will be 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

Not applicable