# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 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 ≥ 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**

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Iran (Islamic Republic of)

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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 ≥ 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
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**Postal code**
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**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**
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## Sponsors / Funding sources

**1**

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**Name of organization / entity**
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research@bums.ac.ir
**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
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Seyed Mohammad Ebnehejazi
**Position**
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**Latest degree**
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Anesthesiology
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## Person responsible for updating data

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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