Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trials of the Effect of intrathecal Magnesium Sulfate on duration of analgesia after cesarean section, with spinal anesthesia, compared with patients undergo a normal routine

Protocol summary

Summary

The aim of this study is to evaluate intrathecal effect of sulfate magnesium on the duration of analgesia. The study population includes all women admitted to Jahrom Peymanieh hospital for Caesarean Section with spinal anesthesia and do not have exclusion criteria. The sample size is estimated to be 69 people. Before surgery, women divided into three groups with throwing dice: a control group and two intervention groups. In the control group (I), 2 ml Marcaine 0.5% and 0.8 mL of normal saline was injected into the mother. In the intervention group (II), the mother received 2 ml Marcaine 0.5% plus 50 mg (0.5 mL) sulfate magnesium with 0.3 ml normal saline. In the intervention group (III) 2 ml of Marcaine 0.5% plus 80 mg (0.8 mL) sulfate magnesium was injected to the mother. From time of Su-Mg injection until the time that the patient experiences the pain for the first time, duration of analgesia was recorded. In order to prevent complications sulfate magnesium injection, the mothers were monitored for 48 hours. All women should give their informed consent for the study. Addicted patients or those who are long-term user of narcotics or painkillers, those suffering from unstable hemodynamic condition, the change of spinal anesthesia to general anesthesia and those who lack mental health were excluded from the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101914049N4**
Registration date: **2017-02-08, 1395/11/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-02-08, 1395/11/20

Registrant information

Name

Ali Abbasi Jahromi

Name of organization / entity

Jahrom University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 79 1334 1501

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abbasija@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Jahrom University of Medical Sciences

Expected recruitment start date

2014-10-22, 1393/07/30

Expected recruitment end date

2016-10-04, 1395/07/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trials of the Effect of intrathecal Magnesium Sulfate on duration of analgesia after cesarean section, with spinal anesthesia, compared with patients undergo a normal routine

Public title

The Effect of intrathecal Magnesium Sulfate on duration

of analgesia after cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All the patients who are going to do cesarean section at Motahari hospital affiliated to Jahrom University of Medical Sciences, can receive spinal anesthesia, Informed consent for participation in this study. Exclusion criteria: education under primary school, chronic pains and cancer, lack of mental and psychological health, chronic use of painkillers and narcotics, Unstable hemodynamic status, expressing disagreement for continuing the research.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **69**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

For blinding in the present study, a double-blind method is used in a way that (1) the person who reviews the results and (2) the person who performs the injections are unaware of which patients did not received sulfate magnesium and which ones did not have any distilled water

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Jahrom University of Medical Sciences

Street address

School of medicine, Motahhari Blvd, Jahrom

City

Jahrom

Postal code

Approval date

empty

Ethics committee reference number

jums.REC.1392.069

Health conditions studied

1

Description of health condition studied

Scores Pain after injection of sulfate magnesium

ICD-10 code

R52.0

ICD-10 code description

Acute pain

2

Description of health condition studied

duration of analgesia after injection of sulfate magnesium

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

duration of analgesia

Timepoint

The first time of pain by mother

Method of measurement

According to time

Secondary outcomes

1

Description

Vital Signs

Timepoint

Every 4 hours after surgery Within 48 hours(2 days)

Method of measurement

Monitoring Blood pressure, Heart Rate, Breathing

Intervention groups

1

Description

Intervention group: In the first intervention group, the patient received 2 cc Bupivacaine 0.5%+ 0.3 cc normal saline+0.5 cc magnesium sulfate 10% (group M50) at the beginning of surgery and after entering the maternity ward; the score of pain, duration of analgesia and Hemodynamic signs measured and recorded at mentioned time.

Category

Treatment - Drugs

2

Description

Control group: patients received 2 cc Bupivacaine 0.5%+

0.8 cc normal saline at the same time with the start of surgery and their score of pain, duration of analgesia and Hemodynamic signs recorded after entering maternity ward.

Category

Placebo

3

Description

Intervention group: In the second intervention group, the patient received 2 cc Bupivacaine 0.5%+ 0.8 cc magnesium sulfate 10% (group M80) at the beginning of surgery and after entering the maternity ward; the score of pain, duration of analgesia and Hemodynamic signs measured and recorded at mentioned time.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari Hospital

Full name of responsible person

Farzaneh Mehran

Street address

Motahhari Blvd, Jahrom

City

Jahrom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Jahrom University of Medical Sciences

Full name of responsible person

Solh Ju Kavos

Street address

Vice chancellor for research, Jahrom University of Medical Sciences, Motahhari Blvd, Jahrom

City

Jahrom

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Jahrom University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Farzaneh Mehran

Position

Anesthesia Undergraduate Student

Other areas of specialty/work

Street address

Nursing and Midwifery College, Motahhari Blvd, Jahrom

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Abbasi Jahromi Ali

Position

Faculty member

Other areas of specialty/work

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty