Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of intrathecal Midazolam in the severity of pain in Cesarean Section: A randomized controlled trial

Protocol summary

Summary

The objective of this study is to determine the effect of Midazolam in in the severity of pain in Cesarean Section (C/S). The total sample size is 124 pregnant patients who will admit In Imam Reza Hospital, Kermanshah University of Medical Science will participate in this study. the patients will divided in two groups that included experimental group and the control group. Patients in the experimental group will received Bupivacaine plus intrathecal Midazolam. Bupivacaine plus normal saline will used in control group. The main outcome measure of pain is Verbal Numerical Rating Scale(VNRS) measured in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807121310N4**
Registration date: **2010-03-31, 1389/01/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-03-31, 1389/01/11

Registrant information

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Alireza Ahmadi
Name of organization / entity
Kermanshah University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2007-12-10, 1386/09/19

Expected recruitment end date

2009-12-10, 1388/09/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intrathecal Midazolam in the severity of pain in Cesarean Section: A randomized controlled trial

Public title

The effect of intrathecal Midazolam in the severity of pain in Cesarean Section: A randomized controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included: No presence of severe spinal lesion, No presence of abscess or infection of skin and soft tissue in the location of needle insertion, No presence of sever anxiety and restlessness, No presence of Central Nervous System lesion, No presence of peripheral nerve lesion, No presence of significant mental disorders or drug abuse, Age 18-45 year. Exclusion criteria: severe spinal lesion, abscess or infection of skin and soft tissue in the location of needle insertion, sever anxiety and restlessness, Central Nervous System lesion, presence of peripheral nerve lesion, presence of significant mental disorders or drug abuse. Age less than 18 or more than 45 years old.

Age

From **18 years** old to **45 years** old

Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **124**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kermanshah University of Medical Sciences
Street address
Kermanshah University of Medical Sciences
City
Kermanshah
Postal code
6718818838
Approval date
2007-06-02, 1386/03/12
Ethics committee reference number
86118

Health conditions studied

1

Description of health condition studied
Pain in caesarean section
ICD-10 code
O82.0
ICD-10 code description
Delivery by elective caesarean section

Primary outcomes

1

Description
Severity of pain
Timepoint
5 min, 15 min, 30 min 1 hour, 2 hour and 4 hour aftercaesarean section
Method of measurement
Verbal Numerical Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group(62 patients) will received Bupivacaine (12.5 mg) plus intrathecal Midazolam (0.13 mg/kg) intratechally.
Category
Treatment - Drugs

2

Description
Bupivacaine (12.5 mg) plus normal saline (0.5-1 ml) will used in control group (62 patients),intratechally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital, Kermanshah University of Medical Sciences
Full name of responsible person
Ali karbasfrushan
Street address
Imam reza Hospital.
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Najafi
Street address
Deputy of Research, Kermanshah University of Medical Sciences
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Ali karbasfrushan, MD

Position
Anesthesiologist

Other areas of specialty/work

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Resident of Anesthesiology

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