

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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 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 be divided into two groups that included the experimental group and the control group. Patients in the experimental group will receive Bupivacaine plus intrathecal Midazolam. Bupivacaine plus normal saline will be used in the 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

Name

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Name of organization / entity

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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 severe 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, severe 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
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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