

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of the effects of midazolam and sufentanil combined with intrathecal bupivacaine on the quality of postoperative analgesia and complications in elective cesarean

Protocol summary

Summary

Objectives: With due attention to this matter that there is not any study which assessed the effects of intrathecal midazolam or sufentanil with bupivacaine and bupivacaine alone and its analgesia and adverse effects including respiratory depression, itching, nausea and vomiting simultaneously, so we evaluated these effects in this study. **Study Design** In a randomized clinical trial all patients who candidate for elective cesarean section with spinal anesthesia and fulfilled inclusion criteria enrolled in study. The patients divided in three groups, first group received bupivacaine 0.5% plus normal saline .9%, second group received bupivacaine 0.5% plus midazolam and third group received bupivacaine 0.5% plus normal saline and sufentanil intrathecal. **Participants, Inclusion and Exclusion criteria:** All women who are candidate for elective cesarean section enrolled in study. **Inclusion criteria:** there was not any contraindication for spinal anesthesia and or any allergy to local anesthetics and other drugs which used in study, patients had not neuropathy and had written consent for spinal anesthesia. Patients with gastrointestinal disease , premature infants under 36 weeks , women who have received anti-nausea medication 24 hours before surgery , hypertension during pregnancy , and if any problems occur during cesarean section are excluded . If the patient has pain during surgery will received narcotic analgesics and excluded from study. **Interventions:** The patients were randomly divided into three groups, the first group received bupivacaine 0.5% 2.5 ml plus 1 ml of 0.9% normal saline, the second group bupivacaine 0.5% 2.5ml plus midazolam 0.02mg/kg and third group 2.5ml bupivacaine 0.5% plus 0.7cc of normal saline 0.9% and 1.5 microgram sufentanil intrathecally. After interathecal injection in sitting position patient was immediately placed in a supine position and measures the time to reach the level of anesthesia to T10 and motor block as

well. The mean arterial blood pressure and heart rate before and after anesthesia measure every 3 minutes. Apgar scores at 1 and 5 minutes after delivery evalutaed and recorded. The main outcome variables: Hypotension (decreasing of systolic blood pressure equal to 20%), heart rate below 45 beats per minute, nausea and vomiting, chills, itching time of T10 perception after surgery, patients need to narcotics analgesics were evaluated and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013052813488N1**

Registration date: **2013-11-22, 1392/09/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-22, 1392/09/01

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Semnan Unoversity of

Expected recruitment start date

2012-09-05, 1391/06/15

Expected recruitment end date

2013-10-07, 1392/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of midazolam and sufentanil combined with intrathecal bupivacaine on the quality of postoperative analgesia and complications in elective cesarean

Public title

The effects of sufentanil and midazolam combined with bupivacaine on analgesia and complications after cesarean

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: There was not any contraindication for spinal anesthesia; patients have not any allergy to local anesthetics and other drugs which used in study; patients had not neuropathy. Exclusion criteria: Gastrointestinal disease; premature infants under 36 weeks; use the anti-nausea medication during 24 hours before surgery; hypertension during pregnancy; any problems occur during cesarean section; pain during surgery.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 75

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Semnan University of Medical Sciences

Street address

Basidj Boulevard

City

Semnan

Postal code**Approval date**

2013-03-10, 1391/12/20

Ethics committee reference number

91/4352

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

analgesia after cesarean section

ICD-10 code

074

ICD-10 code description

Complications of anaesthesia during labour and delivery

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

time to reach the level of anesthesia to T10

Timepoint

every 3 minutes

Method of measurement

Clinical examination

Secondary outcomes**1****Description**

APGAR score, hypotension after surgery, time of pain initiation

Timepoint

after surgery

Method of measurement

Clinical examination

Intervention groups**1****Description**

The first group received bupivacaine 0.5% 2.5 ml plus 1 ml of 0.9% normal saline intrathecally.

Category

Prevention

2

Description

The second group received bupivacaine 0.5% 2.5ml plus midazolam 0.02mg/kg intrathecally.

Category

Prevention

3

Description

Third group received 2.5ml bupivacaine 0.5% plus 0.7cc of normal saline 0.9% and 1.5 microgram sufentanil intrathecally.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al Momenin Hospital

Full name of responsible person

Raheleh Azadi

Street address

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Semnan Unoversity of Medical Sciences

Full name of responsible person

Raheb Ghorbani

Street address

Basidj Boulevard

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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 of Semnan Unoversity 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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Person responsible for updating data

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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