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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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Semnan Unoversity of

Medical Sciences

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 Boulvard
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
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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 Boulvard
City
Semnan
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

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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