Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

A Clinical trial Of Analgesic Effects, Hemodynamic Changes And Postoperative Nausea And Vomiting After Intrathecal Injection Of Bupivacaine Plus Midazolam , Bupivacaine Plus Pethidine Or Bupivacaine Alone In Elective Cesarean Section

Protocol summary

Summary

Females with full-term pregnancy and American Society of anesthesiologists physical status I or II who undergo a non-emergent cesarean section (elective cesarean, previous cesarean, cephalopelvic disproportion, malpresentation) will recruited in this study. The sample size calculated to be 90 women. After informing the participants about the goals and the methodology of the study, informed consent will be obtained and the participants will randomly allocated to three groups with 30 women. group I (control) each woman will receive 10 milligram bupivacaine 5%, group II 10 milligram bupivacaine 5% plus 25 milligram pethidine and group III 10 milligram bupivacaine 5% plus 2 milligram midazolam. All interventions would be intrathecal. Before spinal block, 15 mg/kg serum ringer will be infused to each patient. Thereafter, the patient will be placed in the sitting position and intrathecal injection will be performed by an anesthesiologist via a 23-G needle. After injection, the patient will be placed in the supine position. Blood pressure will be measured once before injection and then with 15 minutes intervals until end of the operation and 30 minutes after that. Also, heart rate, frequency of nausea and vomiting and the time of analgesia and the need for first dose of analgesic agents will be documented and compared in each group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102719145N2**
Registration date: **2014-11-12, 1393/08/21**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2014-11-12, 1393/08/21

Registrant information

Name
Afshin Khani
Name of organization / entity
Babol University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 11 3219 0971
Email address
afshinkhani@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology of Fasa University of Medical Sciences

Expected recruitment start date

2014-10-20, 1393/07/28

Expected recruitment end date

2014-12-20, 1393/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical trial Of Analgesic Effects, Hemodynamic Changes And Postoperative Nausea And Vomiting After Intrathecal Injection Of Bupivacaine Plus Midazolam , Bupivacaine Plus Pethidine Or Bupivacaine Alone In

Elective Cesarean Section

Public title
Effect of Intrathecal midazolam , Pethidine and Bupivacaine on Analsgesia, Hemodynamic Status and Nausea and Vomiting After Elective Cesarean Section
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Full-term pregnant women; candidate for non-emergent cesarean section (elective cesarean, previous cesarean, cephalopelvic disproportion, malpresentation); American Society of Anesthesiologists physical status I or II Exclusion Criteria: contraindication for intrathecal injection; allergy to midazolam or pethidine; systemic diseases (such as diabetes, hypertension and preeclampsia)
Age
From **20 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **90**
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
Fasa University of Medical Sciences
Street address
Deputy of Research and Technology, Fasa University of Medical Sciences, Fasa
City
Fasa
Postal code
, Deputy of Research
Approval date
2014-09-23, 1393/07/01
Ethics committee reference number
E-9213

Health conditions studied

1

Description of health condition studied
Spinal Block in elective cesarean
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain
Timepoint
Immediately after termination of spinal block, thereafter with 30 minutes intervals until 4 hours
Method of measurement
Visual Analog Scale

2

Description
Need for first dose of analgesic agent
Timepoint
Immediately after termination of spinal block, thereafter with 30 minutes intervals until 4 hours
Method of measurement
Patient's request

3

Description
Heart Rate
Timepoint
Before operation, immediately after spinal block, thereafter with 15 minute intervals until 90 minute,immediately after termination of spinal block, 30 minutes after termination of spinal blocks
Method of measurement
Heart Rate monitoring

4

Description
Blood Pressure
Timepoint
Before operation, immediately after spinal block, thereafter with 15 minute intervals until 90 minute, immediately after termination of spinal block, 30 minutes after termination of spinal blocks
Method of measurement
Blood Pressure monitoring

5

Description
Nausea and Vomiting
Timepoint
Immediately after spinal block, 30 minutes later, one, two and four hours later
Method of measurement

Observing the patient

Secondary outcomes

empty

Intervention groups

1

Description
Group I (control): 10 milligram bupivacaine 5%
Category
Treatment - Drugs

2

Description
Group II (intervention): 10 milligram bupivacaine 5% plus 25 milligram pethidine
Category
Treatment - Drugs

3

Description
Group III (intervention): 10 milligram bupivacaine 5% plus 2.5 miligram midazolam
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital of Fasa
Full name of responsible person
Aliasghar Karimi
Street address
Deputy of research and technology, Fasa University of Medical Sciences, Avicenna Sq, Fasa
City
Fasa

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Ehsan Bahramali
Street address
Deputy of research and technology, Fasa University of Medical Sciences, Avicenna Sq, Fasa
City
Fasa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Fasa 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
Fasa University of Medical Sciences
Full name of responsible person
Mahshid Abdollahi
Position
Student
Other areas of specialty/work
Street address
Fasa University of Medical Sciences, Avicenna Sq, Fasa
City
Fasa
Postal code
Phone
+98 73 1221 6300
Fax
Email
abdollahi.m4@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Habib Zakeri
Position
Anesthesiologist
Other areas of specialty/work
Street address
Fasa University of Medical Sciences, Avicenna Sq, Fasa
City
Fasa
Postal code
Phone
+98 73 1221 6300
Fax
Email
zakerihabib@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Afshin Khani

Position
Student

Other areas of specialty/work

Street address
Babol University of Medical Sciences, Babol

City
Babol

Postal code

Phone
+98 113219071

Fax

Email
afshinkhani@mubabol.ac.ir

Web page address

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