

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Analgesia, 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 milligram 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

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abdollahi.m4@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

Habib Zakeri

##### Position

Anesthesiologist

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## **Person responsible for updating data**

### **Contact**

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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*