

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparison of the effects of hyperbaric and isobaric bupivacaine on the Bispectral Index in parturients undergoing cesarean section with spinal anesthesia

#### Protocol summary

##### Summary

The aim of this double-blinded randomized clinical trial was evaluation the efficacy of hyperbaric and isobaric bupivacaine on Bispectral Index in parturients undergoing elective cesarean section with spinal anesthesia. A total of 84 ASA physical status I-II women undergoing elective cesarean section with spinal anesthesia were randomized to 2 groups: 1- 2.5 cc hyperbaric bupivacaine 0.5%; 2- 2.5 cc isobaric bupivacaine 0.5%. All parturients received 10 ml/kg ringer lactate solution. Then spinal anesthesia was done in sitting position using 25 G sprotte needle. Participants were including parturients with ASA physical status I-II, scheduled for elective cesarean section, under spinal anesthesia and excluded with suspicious to bleeding disturbances, atopia, diabetes mellitus, presence of liver or kidney diseases, drugs abuse, complicated pregnancy and preeclampsia. Bispectral Index (BIS), signal quality index, electromyography and the temperature compared among the groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201201162405N9**

Registration date: **2012-01-29, 1390/11/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-01-29, 1390/11/09

##### Registrant information

##### Name

Mitra Jabalameli

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1668 7472

##### Email address

jabalameli@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

##### Expected recruitment start date

2009-06-27, 1388/04/06

##### Expected recruitment end date

2011-04-27, 1390/02/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effects of hyperbaric and isobaric bupivacaine on the Bispectral Index in parturients undergoing cesarean section with spinal anesthesia

##### Public title

The effects of hyperbaric and isobaric bupivacaine on the Bispectral Index in cesarean section with spinal anesthesia

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion Criteria: Parturients; ASA physical status I-II; scheduled for elective cesarean section; using spinal

anesthesia; Exclusion Criteria: suspicious to bleeding disturbances; atopia; diabetes mellitus; presence of liver or kidney diseases; drugs abuse; complicated pregnancy; preeclampsia

#### Age

From **15 years** old to **45 years** old

#### Gender

Female

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **84**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice-chancellor for Research, Ethics committee of Isfahan University of Medical Sciences

##### Street address

Vice-chancellor for Research, Gostaresh Building, Isfahan University of Medical Sciences

##### City

Isfahan

##### Postal code

#### Approval date

2009-07-20, 1388/04/29

#### Ethics committee reference number

22996

## Health conditions studied

### 1

#### Description of health condition studied

Complications of anesthesia during pregnancy

#### ICD-10 code

O29.8

#### ICD-10 code description

Other complications of anesthesia during pregnancy

## Primary outcomes

### 1

#### Description

Bispectral Index

#### Timepoint

at the baseline ( 2 h before surgery) and then 5th, 10th, 15th, 30th, 45th, 60th, 90th and 120th minutes after spinal injection

#### Method of measurement

with attachment of probes of Cerebral Status Monitoring to the parturient

## Secondary outcomes

### 1

#### Description

Signal Quality Index

#### Timepoint

at the baseline ( 2 h before surgery) and then 5th, 10th, 15th, 30th, 45th, 60th, 90th and 120th minutes after spinal injection

#### Method of measurement

with attachment of probes of Cerebral Status Monitoring to the parturient

### 2

#### Description

Electromyography

#### Timepoint

at the baseline ( 2 h before surgery) and then 5th, 10th, 15th, 30th, 45th, 60th, 90th and 120th minutes after spinal injection

#### Method of measurement

with attachment of probes of Cerebral Status Monitoring to the parturient

### 3

#### Description

Temperature

#### Timepoint

at the baseline ( 2 h before surgery) and then 5th, 10th, 15th, 30th, 45th, 60th, 90th and 120th minutes after spinal injection

#### Method of measurement

with tympanometer from the tympanic membrane

## Intervention groups

### 1

#### Description

2.5 cc hyperbaric bupivacaine 0.5%. Duration of intervention: single dose in 10 seconds spinal injection. Duration of treatment: During spinal anesthesia in operating room

#### Category

Treatment - Drugs

## 2

### Description

2.5 cc isobaric bupivacaine 0.5%. Duration of intervention: single dose in 10 seconds spinal injection. Duration of treatment: During spinal anesthesia in operating room

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Beheshti Medical Center

##### Full name of responsible person

Dr. Mitra Jabalameli

##### Street address

Pol fellezi

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

##### Full name of responsible person

Dr. Payman Adibi

##### Street address

Vice-chancellor for Research, Gostaresh Building, Isfahan University of Medical Sciences, Hezar Jarib St.

##### City

Isfahan

##### 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, Isfahan 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

Isfahan University of Medical Sciences

#### Full name of responsible person

Dr. Mitra Jabalameli

#### Position

Specialist and Associate professor of Anesthesia and intensive care

#### Other areas of specialty/work

#### Street address

Department of Anesthesia and intensive care, Alzahra General Hospital, Sofe Boulevard

#### City

Isfahan

#### Postal code

#### Phone

+98 3116255551532

#### Fax

#### Email

jabalameli@med.mui.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Isfahan University of Medical Sciences

#### Full name of responsible person

Dr. Mitra Jabalameli

#### Position

Specialist and Associate professor of Anesthesia and intensive care

#### Other areas of specialty/work

#### Street address

Department of Anesthesia and intensive care, Alzahra General Hospital, Sofe Boulevard

#### City

Isfahan

#### Postal code

#### Phone

+98 3116255551532

#### Fax

#### Email

jabalameli@med.mui.ac.ir

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Isfahan University of Medical Sciences

#### Full name of responsible person

Dr. Mitra Jabalameli

#### Position

Specialist and Associate professor of Anesthesia and intensive care

#### Other areas of specialty/work

#### Street address

Department of Anesthesia and intensive care, Alzahra General Hospital, Sofe Boulevard

#### City

Isfahan

**Postal code**

772

**Phone**

+98 31162555551532

**Fax**

+98 31 1626 5773

**Email**

jabalameli@med.mui.ac.ir

**Web page address**

www.mui.ac.ir

**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*