Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 receieved 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. Bispecteral 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

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Name of organization / entity

Isfahan University of Medical Sciences

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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

Bispecteral 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 isorbaric 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
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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, 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
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Full name of responsible person
Dr. Mitra Jabalameli

Position
Specialist and Associate professor of Anesthesia and intensive care

Other areas of specialty/work

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Person responsible for scientific 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