Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Effect of Baricity of Bupivacaine on the Maternal Hemodynamics during Spinal Anesthesia for Cesarean section

Protocol summary

Summary

Baricity is an important determinant of block characteristics of the spinal anesthesia for cesarean section. The aim of his study to compare the maternal hemodynamic effects and side effects of intrathecally administered isobaric or hyperbaric bupivacaine (both with fentanyl) in parturients undergoing elective cesarean delivery. In this double-blind randomized study, 84 parturient undergoing elective cesarean delivery are randomized to receive a hyperbaric (control group; n=42) or isobaric (study group; n=42) intrathecal solution of 10mg bupivacaine and 15 µg fentanyl during spinal anesthesia is induced in the sitting position. Data collection is included maternal hemodynamics, episodes of hypotension, vasoconstrictor use, leveL OF sensory, and motor block.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201401287013N7**
Registration date: **2014-02-12, 1392/11/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-12, 1392/11/23

Registrant information

Name

Simin Atashkhoei

Name of organization / entity

Tabriz University of Medical Siences

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Recruitment status

Recruitment complete

Funding source

Research Vice Chancellor of Tabriz University of Medical Sciences

Expected recruitment start date

2013-12-09, 1392/09/18

Expected recruitment end date

2014-09-08, 1393/06/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Baricity of Bupivacaine on the Maternal Hemodynamics during Spinal Anesthesia for Cesarean section

Public title

Effect of local anesthetic baricity on control of maternal hypotension after spinal anesthesia for cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ASA class I; term pregnancy; aged 18-40 years; scheduled for elective cesarean; scheduled for spinal anesthesia Exclusion criteria: weight >85kg; Height >170cm and < 150cm; contraindication for spinal anesthesia; history of systemic or psychopathic disorders; preeclampsia or eclampsia; allergy to local anesthetics

Age

From **18 years** old to **40 years** old

Gender

Female

Phase
N/A
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
Research Vice Chancellor of Tabriz University of Medical Sciences
Street address
Research Vice Chanceller; Tabriz University; Daneshgah Street; Tabriz
City
Tabriz
Postal code
Approval date
2013-12-09, 1392/09/18
Ethics committee reference number
92152

Health conditions studied

1

Description of health condition studied
Hypotension after spinal anesthesia
ICD-10 code
I95.2
ICD-10 code description
Hypotension due to drugs

Primary outcomes

1

Description
Blood pressure
Timepoint
Baseline and every 2 minutes after spinal anesthesia to 10 min and then every 5 min to end of surgery
Method of measurement
Manometer

Secondary outcomes

1

Description
Total dose of vasoconstrictors
Timepoint
After spinal anesthesia to end of operation
Method of measurement
Doses of medicatins by mg or ug

Intervention groups

1

Description
In the study group (n=42)0.5 % of isobaric bupivacaine 10 mg with fentanyl 15 µg during spinal anesthesia is administered.
Category
Prevention

2

Description
]n the control group (n=42) hyperbaric bupivacaine 10 mg with fentanyl 15 µg during spinal anesthesia is administered.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Dr. Simin Atashkhoyi
Street address
Alzahra Hospital, South Artesh Ave; Tabriz
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Vice Chancellor of Tabriz University of Medical Sciences
Full name of responsible person
Dr. Rashidi
Street address
Research Vice Chancellor; Daneshgah Street; Tabriz

City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Vice Chancellor of Tabriz 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
Tabriz University of Medical Sciences
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Position
Anesthesiologist/ Professor
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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