

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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 Sciences

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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 Chancellor; 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 medications 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

In 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

Tabriz

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

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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