Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Effect of Position during Spinal Anesthesia for Cesarean section on Maternal Hemodynamics

Protocol summary

Summary

During cesarean delivery the position of the patient may be particularly important because a different spread of the block may affect the incidence and severity of maternal hypotension. The aim of this study is to compare the maternal hemodynamic effects and side effects of intrathecally administered hyperbaric bupivacaine with fentanyl in the sitting or lateral decubitus position for placement of spinal needle during elective cesarean delivery. In this double-blind prospective study, 76 parturents aged 18-40 years and ASA class I, undergoing elective cesarean delivery are randomized to receive a hyperbaric, intrathecal solution of 10mg bupivacaine and 15µg fentanyl during spinal anesthesia induced in either the sitting or right lateral position. After an intrathecal injection using spinal technique patients is placed in the supine wedged position. Data collection is included sensory level, motor block, incidence and severity of hemodynamic changes, and vasoconstrictor use.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402017013N8**
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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atashkhoii@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Vice Chancellor of Tabriz University of Medical Sciences

Expected recruitment start date

2013-11-27, 1392/09/06

Expected recruitment end date

2014-08-27, 1393/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Position during Spinal Anesthesia for Cesarean section on Maternal Hemodynamics

Public title

Effect of Position during Spinal Anesthesia for Cesarean section on Maternal Hemodynamics

Purpose

Prevention

Inclusion/Exclusion criteria

In inclusion criteria: aged 18-40 years; scheduled for cesarean section; scheduled for spinal anesthesia
Exclusion criteria: gestational age 36 wk; History of systemic (cardiovascular, respiratory, renal , ...) or psychiatric disorders, hypertension(BP> 140/90 mmHG) Allergy to bupivacaine; contraindication for spinal anesthesia; emergency cesarean section, fetal

problems(IUGR, Asphyxia,...) □

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: **76**

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
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
2013-11-27, 1392/09/06

Ethics committee reference number
92137

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
mmHg

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=38) 0.5 % of hyperbaric bupivacaine 10 mg with fentanyl 15 µg during spinal anesthesia in lateral decubitos position is administered.

Category
Treatment - Drugs

2

Description
]n the control group (n=38) 0/5 ofhyperbaric bupivacaine 10 mg with fentanyl 15 µg during spinal anesthesia in sitting position 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, Tabriz University of Medical

Sciences

Full name of responsible person

Dr. Rashidi

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Research Vice Chancellor, Tabriz University, 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, 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

Full name of responsible person

Dr. Simin Atashkhoyi

Position

Anesthesiologist/ Professor

Other areas of specialty/work

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Other areas of specialty/work

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City

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Phone

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Fax

Email

Web page address

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