Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparision of hemodynamic effect in lateral tilt before and after spinal anesthesia during elective

Protocol summary

Study aim
Comparing the effects of left lateral tilt before versus after spinal anesthesia on the hemodynamic parameters of mothers undergoing elective cesarean section

Design
Controlled, parallel-group, double-blind, randomized clinical trial, phase not applicable on 110 patients. Random Allocation Software was used for randomization.

Settings and conduct
This clinical trial will be conducted on 110 pregnant women undergoing elective cesarean section at Kowsar Hospital, Urmia. Following random allocation, a 15-degree left lateral tilt will be applied before spinal anesthesia in one group and after it in the other. For blinding, the outcome assessor (who records hemodynamic parameters, is absent during tilt positioning, and is unaware of group allocation) and the data analyst (via coded datasets as groups A and B) are blinded to the intervention; however, the patients and the administering anesthesiologist are not blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 40 years, term singleton pregnancy (37 to 40 weeks), candidate for elective cesarean section, ASA physical status class I or II, and written informed consent. Exclusion criteria: Cardiovascular diseases or chronic hypertension, morbid obesity (BMI > 40), preeclampsia or eclampsia, coagulation disorders or active bleeding, allergy to local anesthetics, and need for general anesthesia.

Intervention groups
Group 1: 15° left lateral tilt applied before spinal anesthesia. Group 2: 15° left lateral tilt applied after spinal anesthesia. In both groups, standard spinal anesthesia is performed with 2 mL of 0.5% hyperbaric bupivacaine plus 20 µg fentanyl via a 25G spinal needle at the L3-L4 or L4-L5 interspace.

Main outcome variables
Systolic blood pressure; diastolic blood pressure; mean arterial pressure (MAP); heart rate; incidence of hypotension; incidence of bradycardia; need for vasopressors

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260425069157N4**
Registration date: **2026-10-25, 1405/08/03**
Registration timing: **prospective**

Last update: **2026-10-25, 1405/08/03**
Update count: **0**

Registration date
2026-10-25, 1405/08/03

Registrant information
Name
Roghayea Neisari
Name of organization / entity
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Recruitment status
Not yet recruiting
Funding source

Expected recruitment start date
2026-11-22, 1405/09/01
Expected recruitment end date
2027-06-21, 1406/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparision of hemodynamic effect in lateral tilt before and after spinal anesthesia during elective

Public title
Evaluating the effect of left lateral tilt before and after spinal anesthesia on hemodynamic status of mothers undergoing elective cesarean section

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 40 years Term pregnancy (37-40 weeks of gestation) Candidate for elective (non-emergency) cesarean section Singleton pregnancy ASA physical status I or II Written informed consent to participate in the study
Exclusion criteria:
History of known cardiovascular diseases or chronic hypertension Severe/morbid obesity (Body Mass Index [BMI] > 40 kg/m²) Preeclampsia or eclampsia Known history of allergy to local anesthetics Active bleeding Coagulation disorders (coagulopathy) Conversion or need for general anesthesia

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

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be allocated to the intervention and control groups using block randomization with block sizes of 4 and 6 on an individual basis. Stratified randomization is not used. The random sequence will be generated using Random Allocation Software. To ensure allocation concealment, sequentially numbered, opaque, sealed envelopes (SNOSE) will be utilized. Upon obtaining written informed consent and arrival in the operating room, the envelope corresponding to the patient's number will be opened by an individual independent of the principal investigator to determine the intervention type (left lateral tilt before or after spinal anesthesia)

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a double-blind randomized clinical trial. Due to the physical nature of the intervention (positioning tilt), blinding the patients and the attending anesthesiologist was not feasible. However, to minimize bias, both the outcome assessor (who recorded hemodynamic parameters without knowledge of group allocation timing) and the data analyst (who analyzed coded datasets as groups A and B) were blinded to group allocations.

Placebo
Not used

Assignment
Parallel

Other design features
This is a parallel-group, randomized clinical trial that compares hemodynamic parameters between the two study groups at baseline and every 5 minutes until the end of surgery. The intervention consists of a positioning maneuver (applying a left lateral tilt before or after spinal anesthesia)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Urmia University of Medical Sciences

Street address
Urmia University of Medical Sciences., Emergency Alley., Resalat Boulevard., Urmia

City
Urmia

Province
West Azarbaijan

Postal code
5718748983

Approval date
2026-09-16, 1405/06/25

Ethics committee reference number
IR.UMSU.REC.1405.192

Health conditions studied

1

Description of health condition studied
Hypotension and bradycardia induced by spinal anesthesia during elective cesarean section

ICD-10 code
O29.2

ICD-10 code description
Central nervous system complications of anesthesia during pregnancy

Primary outcomes

1

Description
Systolic Blood Pressure)

Timepoint
Baseline (pre-intervention) and every 5 minutes until the end of surgery
Method of measurement
Standard operating room vital signs monitor

2

Description
Diastolic Blood Pressure
Timepoint
Baseline (pre-intervention) and every 5 minutes until the end of surgery
Method of measurement
Standard operating room vital signs monitor

3

Description
Mean Arterial Pressure (MAP)
Timepoint
Baseline (pre-intervention) and every 5 minutes until the end of surgery
Method of measurement
Standard operating room monitor

Secondary outcomes

1

Description
Heart Rate
Timepoint
Baseline (pre-intervention) and every 5 minutes until the end of surgery
Method of measurement
Standard monitor (ECG / Pulse Oximetry)

2

Description
Incidence of Hypotension
Timepoint
From the onset of spinal anesthesia until the end of surgery
Method of measurement
Recorded via checklist; defined as a decrease of more than 20% from baseline blood pressure

3

Description
Incidence of Bradycardia
Timepoint
From the onset of spinal anesthesia until the end of surgery
Method of measurement
Recorded via checklist; defined as a decrease of more than 20% from baseline heart rate

Intervention groups

1

Description
Intervention group1: Application of a 15° left lateral tilt before spinal anesthesia
Category
Prevention

2

Description
Intervention group2: Application of a 15° left lateral tilt after spinal anesthesia
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Comprehensive Women’s Educational and Medical Center
Full name of responsible person
Dr. Roghayea Neisari
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Sponsors / Funding sources

1

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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
Oroumia University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Roghayea Neisari
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available