Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of sitting and lateral position during spinal anesthesia on maternal Sensory block Level and hemodynamics effect in cesarean section

Protocol summary

Study aim
Comparison of sitting and lateral position during spinal anesthesia on maternal sensory block Level and hemodynamic effects in cesarean section.

Design
106 patients are randomly assigned into 4 blocks in a randomized, clinical trial, and in one of two positions, sitting and right lateral are under spinal anesthesia.

Settings and conduct
patients undergoing cesarean section at Fatemiyeh Hospital of Hamadan randomly placed in one of the two sitting and right-sided positions under spinal anesthesia and return immediately in supine position, and the vital signs and the maximum sensory level and onset time of anesthesia are evaluated by an assessment who does not know the patients' classification during spinal anesthesia.

Participants/Inclusion and exclusion criteria
Inclusin Criteria: parturients aged 18 to 45 years old; Candidates for cesarean section under spinal anesthesia; ASA Physical Class 1 and 2. Exclusion Criteria: Heart disease; Hypertension; Eclampsia & pre-eclampsia; Diabetes; Those who are reluctant to continue to participate in the study; Patients who have failed spinal anesthesia and undergo general anesthesia; Spinal anesthesia Contraindications (High ICP, coagulation problems, shock, anemia)

Intervention groups
After measuring the initial vital signs, the patients in group A are placed in a sitting position and patients in group B are placed in right lateral position and under spinal anesthesia by an anesthesiologist in L4-L3 space with a spinal quincke needle number 25. After aspiration of the cerebro spinal fluid, 10 mg of 0.5% bupivacaine and 0.5 ml of sufentanil are injected into the sub-arachnoid space, and the patient is placed immediately in the supine position and the vital signs will be registered.

Main outcome variables
Maximum sensory level; Onset time of anesthesia; Blood Pressure; Heart Rate; Nausea & Vomiting; Satisfaction; Atropine &Ephedrine dose

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120915010841N13**
Registration date: **2019-03-04, 1397/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-04, 1397/12/13**
Update count: **0**

Registration date
2019-03-04, 1397/12/13

Registrant information

Name
Nahid Manuchehrian

Name of organization / entity
Hamedan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sitting and lateral position during spinal anesthesia on maternal Sensory block Level and hemodynamics effect in cesarean section

Public title

The effect of Patient's position on post spinal anesthesia hypotension

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

parturients aged 18 to 45 years old Candidates for cesarean section under spinal anesthesia ASA Physical Class 1 and 2

Exclusion criteria:

Heart disease Hypertension Eclampsia & pre-eclampsia Diabetes Those who are reluctant to continue to participate in the study Patients who have failed spinal anesthesia and undergo general anesthesia Spinal anesthesia Contraindications (High ICP, coagulation problems, shock, anemia)

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study , a randomized block design with four replications is used. we provide four paper sheets . We write two letters A and on two other sheets of letter B. We mix the papers together and put them in the drawer of the table.With each of the qualified patients, one of the papers is taken out randomly and will be assigned to one of the two sitting or lateral position groups, depending on whether the drawn sheet is either A or B. After the random drawn out of four sheets, all the papers will be returned to the drawer and again the above procedure will continue for the next four patients until it reaches the sample volume.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients in Group A are in the sitting position and patients in Group B are placed in the right lateral position and they are under spinal anesthesia by anesthesiologist .Then the patients are immediately placed in supine position and evaluate by assessing who does not know the patients' classification and status of patients during spinal anesthesia in the two groups that analyzes the outcomes.In this study, the evaluator and analyzer do not know the type of patient s position drug spinal anesthsia.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan university of medical sciences

Street address

Mahdieh Street

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2018-09-01, 1397/06/10

Ethics committee reference number

IR.UMSHA.REC.1397.414

Health conditions studied

1

Description of health condition studied

Hypotension & sensory block level during spinal anesthesia under different positions in c/s

ICD-10 code

074.6

ICD-10 code description

En Other complications of spinal and epidural anaesthesia during labour and delivery

Primary outcomes

1

Description

Maximum sensory level

Timepoint

Every minute to 5 minutes

Method of measurement

Determination of sensory level by needle (Pinprick)

2

Description
Onset time of sensory block
Timepoint
Every minute until the sensory block is fixed
Method of measurement
In minutes using the clock

3

Description
Systolic and Diastolic Blood Pressure
Timepoint
Every two minutes for 10 minutes and then every 10 minutes to 60 minute
Method of measurement
Non-invasive automatic barometric device

4

Description
Heart Rate
Timepoint
Every two minutes for 10 minutes and then every 10 minutes to 60 minute
Method of measurement
Non-invasive automatic barometric device

Secondary outcomes

1

Description
Nausea and Vomiting
Timepoint
During surgery
Method of measurement
View and ask the patient

2

Description
satisfaction
Timepoint
End of surgery
Method of measurement
Question from the patient

3

Description
Need for ephedrine
Timepoint
End of surgery
Method of measurement
Calculate consumed ephedrine

4

Description
Need for atropine
Timepoint
End of surgery
Method of measurement
Calculate consumed atropine

Intervention groups

1

Description
Control group: After measuring and recording the initial vital signs, the patients in group A are placed in a sitting position and under spinal anesthesia by an anesthetist in L4-L3 (mid line) with a spinal quincke needle number 25. After aspiration of the cerebro spinal fluid, 10 mg (2 ml) of 0.5% bupivacaine and 0.5 ml of sufentanil are injected into the sub-arachnoid space, and then the patient is placed immediately in the supine position and the vital signs will be registered.
Category
Prevention

2

Description
Intervention group: After measuring and recording the initial vital signs, the patients in group B are placed in a right lateral position and under spinal anesthesia by an anesthetist in L4-L3 (mid line) with a spinal quincke needle number 25. After aspiration of the cerebro spinal fluid, 10 mg (2 ml) of 0.5% bupivacaine and 0.5 ml of sufentanil are injected into the sub-arachnoid space, and then the patient is placed immediately in the supine position and the vital signs will be registered.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemy Hospital
Full name of responsible person
Nahid Manouchehrian, Anesthesiologist, Assistant Professor of Hamadan University Of Medical Sciences
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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
Hamedan 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
Hamedan University of Medical Sciences
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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