

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Oct 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

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)

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 Manouchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 7012

Email address

manouchehrian@umsha.ac.ir

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 anesthesia.

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

Street address

Fatemy Hospital, Pasdaran Street

City

Hamadan

Province

Hamadan

Postal code

6517789971

Phone

+98 81 3827 7012

Fax

+98 81 3828 3939

Email

hp.fatemieh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Mahdie Street

City

Hamadan

Province

Hamadan

Postal code

6517838678

Phone

+98 81 3838 0717

Fax

+98 81 3838 0130

Email

vc_research@umsha.ac.ir

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

Full name of responsible person

Nahid Manouchehrian

Position

Associate professor of Hamadan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Fatemieh Hospital, Pasdaran Street

City

Hamadan

Province

Hamadan

Postal code

6517789971

Phone

+98 81 3827 7012

Fax

+98 81 3828 3939

Email

manuchehriann@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Nahid Manouchehrian

Position

Associate Professor of Hamadan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Pasdaran Street

City

Hamadan

Province

Hamadan

Postal code

6517789971

Phone

+98 81 3827 7012

Fax

+98 81 3828 3939

Email

manuchehriann@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Nahid Manouchehrian

Position

Associate Professor of Hamadan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Pasdaran Street

City

Hamadan

Province

Hamadan

Postal code

6517789971

Phone

+98 81 3827 7012

Fax

+98 81 3828 3939

Email

manuchehriann@gmail.com

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