Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of spinal anesthesia in L3-L4 and L4-L5 on sensory- motor block and Hemodynamic state in cesarean section

Protocol summary

Study aim
Comparison of spinal anesthesia in L3-L4 and L4-L5 on sensory- motor block and Hemodynamic state in cesarean section.

Design
70 patients were randomly assigned into 4 blocks in a randomized, double blind randomized clinical trial,In one of the two groups, anesthesia occurs at the level of L3-L4 or L4-L5 under spinal anesthesia.

Settings and conduct
In this study, patients aged 18 to 45 years who are candidates for cesarean section who will be referred to the Fatemiyeh Hospital of Hamedan during the study period, will be randomly assigned to randomized allocation blocks by random sampling.

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
Case group: Patients undergoing cesarean section under spinal anesthesia in L3-L4 space. Control group: Patients undergoing cesarean section under spinal anesthesia in L4-L5 space.

Main outcome variables
Sensory block level, motor block level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120915010841N15**
Registration date: **2019-03-27, 1398/01/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-27, 1398/01/07**
Update count: **0**

Registration date
2019-03-27, 1398/01/07

Registrant information

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Name of organization / entity
Hamedan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-11, 1397/12/20

Expected recruitment end date
2021-03-05, 1399/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of spinal anesthesia in L3-L4 and L4-L5 on sensory- motor block and Hemodynamic state in cesarean section

Public title

Spinal anesthesia in L3-L4 and L4-L5 on sensory- motor block and Hemodynamic state in cesarean section

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

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **70**

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 groups, anesthesia at the level of L3-L4 or L4-L5, 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)

Double blinded

Blinding description

In both groups, the patient and the anesthetist nurse who entered the information in the questionnaire, none of the level of SCI performed by the anesthetist was unaware. In addition, the analyzer will not know the results of encoding the intervention and comparison groups.

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

2019-03-09, 1397/12/18

Ethics committee reference number

IR.UMSHA.REC.1397.958

Health conditions studied

1

Description of health condition studied

Spinal anesthesia in cesarean section

ICD-10 code

o74.6

ICD-10 code description

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

after delivery

Method of measurement

View and ask the patient

2

Description

Need for ephedrine

Timepoint

End of surgery

Method of measurement

Calculate consumed ephedrine

3

Description

Need for atropine

Timepoint

End of surgery

Method of measurement

Calculate consumed atropine

Intervention groups

1

Description

Intervention group: Patients undergoing cesarean section under spinal anesthesia in L3-L4 space.

Category

Prevention

2

Description

Control group: Patients who underwent cesarean section under spinal anesthesia in L4-L5 space.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Nahid Manouchehrian, Anesthesiologist, Assistant Professor of Hamadan University Of Medical Sciences

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Fatemy Hospital, Pasdaran Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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
Full name of responsible person
Nahid Manouchehrian
Position
Associate professor of Hamadan 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