Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Oct 2026

Evaluation of the effect of 0.2 ml of cerebro-spinal fluid aspiration at the end of intrathecal injection of bupivacaine 0.5% on the onset time and sensory block level in cesarean section under spinal anesthesia.

Protocol summary

Study aim

Determination of the effect of 0.2 ml of cerebrospinal fluid aspiration at the end of intrathecal injection of bupivacaine 0.5% on the onset time and sensory level in cesarean section under spinal anesthesia.

Design

This clinical trial with a control group with parallel, double-blind, randomized, phase 2-3 groups was performed on 60 patients and randomization block was used for randomization.

Settings and conduct

At the end of the drug injection in spinal anesthesia, in 30pregnant patients in group A (aspiration group), 0.2 ml of CSF is re-aspirated and re-injected into the subarachnoid space and in 30 pregnant patients in group B (without aspiration), without CSF aspiration, the spinal needle is removed and the patient is placed in a supine position.Then the time to reach the maximum level of sensory block (using pinprick), the quality of sensory and motor block (using VAS and bromage score), blood pressure and heart rate at specific times (by non-invasive monitoring of Saadat Model 162 made in Iran) are measured and recorded in a questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Conscious consent to participate in the study; 18 to 46 years old; Term pregnancy (37 weeks and more); Candidate for cesarean section under spinal anesthesia; Exclusion criteria: Cancel the continuation of the plan; Heart and lung diseases, hypertension, diabetes, arrhythmia and heart failure; Multiple pregnancies; Eclampsia and preeclampsia; Contraindications of spinal anesthesia; Emergency C/S

Intervention groups

Patients after spinal anesthesia are randomly assigned to one of the two groups of cerebrospinal fluid aspiration (Intervension group) and without cerebrospinal fluid aspiration (Control group).

Main outcome variables

Time to reach the maximum sensory block and quality of sensory-motor block

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120915010841N25**
Registration date: **2021-09-20, 1400/06/29**
Registration timing: **prospective**

Last update: **2021-09-20, 1400/06/29**
Update count: **0**

Registration date

2021-09-20, 1400/06/29

Registrant information

Name

Nahid Manuchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-22, 1400/06/31

Expected recruitment end date

2022-01-19, 1400/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of 0.2 ml of cerebro-spinal fluid aspiration at the end of intrathecal injection of bupivacaine 0.5% on the onset time and sensory block level in cesarean section under spinal anesthesia.

Public title

Evaluation of csf aspiration in spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Conscious consent to participate in the study 18 to 46 years old Term pregnancy (37 weeks and more) Candidate for cesarean section under spinal anesthesia

Exclusion criteria:

Cancel the continuation of the plan Heart and lung diseases, hypertension, diabetes, arrhythmia and heart failure Multiple pregnancies Eclampsia and preeclampsia Contraindications of spinal anesthesia (high ICP, hypovolemia, anemia, coagulation disorders) Emergency C/S

Age

From **18 years** old to **46 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the quadruple Block Randomization method. For this purpose, we prepare four sheets of paper.Write the letter A on two sheets and the letter B on the other two sheets. Mix the sheets together and place them in the desk drawer. With the referral of each eligible patient, one of the sheets is randomly taken out and based on this sheet is A or B, it will be assigned to one of the two groups of aspiration and non-aspiration. After randomly pulling out all four sheets, all the papers are returned to the drawer and the above procedure will be continued for the next four patients until the desired sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients are placed under spinal anesthesia by an anesthesiologist in a sitting position and based on randomization , the patients undergoing aspiration or non-aspiration of cerebro-spinal fluid at the end of spinal anesthesia and then the vital signs, the level and quality of sensory and motor blocks were measured and recorded by Pinprick, VAS and bromage score by the researcher (intern) who has no information on randomization .

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

2020-10-24, 1399/08/03

Ethics committee reference number

IR.UMSHA.REC.1399.630

Health conditions studied

1

Description of health condition studied

Spinal anesthesia in cesarean sectionکد ICD-10خالی

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Time to reach the maximum level of sensory block

Timepoint

Immediately after spinal anesthesia until the onset of sensory block

Method of measurement

Use the watch to measure time and the needle(pinprick) to determine the sensory block

2

Description
Sensory block quality
Timepoint
Before surgery
Method of measurement
Visual Analog Scale(VAS)

3

Description
Motor block quality
Timepoint
Before surgery
Method of measurement
Bromage score

Secondary outcomes

1

Description
Blood pressure
Timepoint
Every two minutes to 10 minutes, then every 5 minutes to 15 minutes, and every 10 minutes until the end of the surgery.
Method of measurement
Automatic non-invasive blood pressure device

2

Description
Nausea and Vomiting
Timepoint
During and after surgery
Method of measurement
Observation

3

Description
The amount of ephedrine have been consumed
Timepoint
During surgery
Method of measurement
mg

4

Description
The amount of atropine have been consumed
Timepoint
During surgery
Method of measurement
mg

5

Description
Spinal Failure
Timepoint
During surgery
Method of measurement
Pinprick

6

Description
Heart Rate
Timepoint
Every two minutes to 10 minutes, then every 5 minutes to 15 minutes, then every 10 minutes until the end of the surgery
Method of measurement
Pulse oximetry

Intervention groups

1

Description
Intervention group: After receiving 10 ml per kg of serum Ringer, patients were placed in a sitting position and after determining the subarachnoid space with the entry of Quince spinal needle No. 25 at the level of L3-L4 or L4-L5 by an anesthesiologist 10 mg Bupivacaine 0.5% with 2.5 microgram of sufentanil is injected into the subarachnoid space.At the end of the drug injection, in group A (aspiration group), 0.2 ml of CSF is re-aspirated and re-injected into the subarachnoid space, then the spinal needle is removed and the patient is placed in a supine position.
Category
Prevention

2

Description
Control group: After receiving 10 ml per kg of serum Ringer, patients were placed in a sitting position and after determining the subarachnoid space with the entry of Quince spinal needle No. 25 at the level of L3-L4 or L4-L5 by an anesthesiologist 10 mg Bupivacaine 0.5% with 2.5 microgram of sufentanil is injected into the subarachnoid space. At the end of the drug injection, in group B (without aspiration), without CSF aspiration, the spinal needle is removed and then the patient is placed in a supine position.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Nahid Manouchehrian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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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Position
Associate professor
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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