

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of lower limb elevation in prevention of spinal anesthesia-induced maternal hypotension in elective cesarean section

Protocol summary

Study aim

this investigation was planned to evaluate the effect of lower limb elevation to reduce the incidence of spinal anesthesia induced hypotension in cesarean section.

Design

Design: This is a two arm parallel group randomised clinical trial with blinded postoperative care and outcome assessment in which 110 patients will be studied in 2 groups.

Settings and conduct

This investigation will be performed in Fatemeh Hospital, Hamadan. The person who care the patients and the person who analyze the data are blinded to group stratification. After performing spinal anesthesia in sitting position; immediately the patient will be placed in supine or supine with leg elevation position. Non invasive blood pressure monitor, ECG and pulse oximetry will be used for monitoring of vital signs every 2 minutes until delivery and then every 5 minutes until the end of the surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all of the ASA 1 (18-45yr)healthy term parturients candidate for Cesarean section Exclusion criteria: chronic hypertension; preeclampsia; twin pregnancy;, preterm labor; allergy to drugs; cardiovascular disease; renal disease and previous abdominal surgeries with adhesion band and fibrosis

Intervention groups

Intervention group: Immediately after spinal anesthesia injection and in supine position, a wedge with the height of 30 cm was inserted below the patient ankles to place the patients hip in 30 degree semiflexed position and remained in this position until the skin incision and then it was removed. control group: Patient was placed in supine position with no wedge under the ankles.

Main outcome variables

Blood pressure changes after spinal anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120118008768N8**

Registration date: **2018-11-06, 1397/08/15**

Registration timing: **prospective**

Last update: **2018-11-06, 1397/08/15**

Update count: **0**

Registration date

2018-11-06, 1397/08/15

Registrant information

Name

Mahshid Nikooseresht

Name of organization / entity

Hamadan university of Medical Sciences, Faculty of Medicine

Country

Iran (Islamic Republic of)

Phone

+98 81 3823 5383

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-07-22, 1398/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of lower limb elevation in prevention of spinal anesthesia- induced maternal hypotension in elective cesarean section

Public title

The effect of leg elevation on hypotension after spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All of the ASA 1 aged 18-45 yr healthy parturients Single tone term parturients Referred to Fatemeh hospital for elective Cesarean section

Exclusion criteria:

Exclusion criteria: chronic hypertension; ; ; ; allergy to drugs; ; renal disease and pre eclampsia twin pregnancy preterm labor allergy to drugs cardiovascular and pulmonary disease Renal Disease previous abdominal surgeries with adhesion band and fibrosis.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with sealed envelope For this purpose 4 papers were prepared. The letter "I" for Intervention was written on 2 papers and the letter "C" for Comparison was written on two another papers. All 4 sheets were placed in a drawer and for including each patient one sheet was pulled out. According to the letter on the sheet "I" or "C"; the patient was assigned to intervention (leg elevation) or control (supine position) group. All of the four sheets were re-turned to the drawer and this cycle will be continued to meet the calculated sample size.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person who collects data, Data Safety and Monitoring Committee and also the person who analyzes the data are blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee of Ethics in Research, Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street, Hamadan

City

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Province

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Postal code

65178

Approval date

2017-10-14, 1396/07/22

Ethics committee reference number

IR.UMSHA.REC.1396.494

Health conditions studied

1

Description of health condition studied

spinal anesthesia induced hypotension

ICD-10 code

O74.6

ICD-10 code description

Other complications of spinal and epidural anaesthesia during labour and delivery

Primary outcomes

1

Description

spinal anesthesia induced blood pressure change

Timepoint

before performing spinal anesthesia, every 2 minutes until delivery and then every 5 minutes until the end of surgery

Method of measurement

blood pressure was measured with automatic blood pressure device and hypotension was defined as more than 20% decrease of BP compared to baseline

Secondary outcomes

1

Description

Heart rate

Timepoint

before performing spinal anesthesia and then every 5 minutes until the end of surgery

Method of measurement

Electrocardiogram monitoring

2**Description**

nausea

Timepoint

every 5 minutes until the end of surgery Method of measurement

Method of measurement

observation

3**Description**

vomiting

Timepoint

every 5 minutes until the end of surgery

Method of measurement

observation

4**Description**

rescue vasopressor dose

Timepoint

at the end of surgery

Method of measurement

measurement

5**Description**

Neonatal condition

Timepoint

at min 1 and 5 after birth

Method of measurement

Apgar score measurements by observation and physical examination

Intervention groups**1****Description**

Intervention group: Immediately after spinal anesthesia injection, a wedge with 30 cm height will be inserted under both ankles until skin incision.

Category

Prevention

2**Description**

Control group: Immediately after spinal anesthesia, the patients will be placed in supine position.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Fatemieh hospital

Full name of responsible person

Mahshid Nikooseresht

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Pasdaran Street, Shariati square, Hamadan, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Saiid Bashirian

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Hamadan 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

Mahshid Nikooseresht

Position

Associate Professor of Anesthesiology, Fellowship of Pain management

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Anesthesiology Department, Besat Hospital, Shahid Motahari Blvd, Resalat Square, Hamadan

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

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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