

# 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

nikooseresht@umsha.ac.ir

##### 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

Hamadan

##### Province

Hamadan

##### 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

**Street address**

Pasdaran Street, Shariati square, Hamadan, Iran

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**Province**

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**Phone**

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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

**Street address**

Hamadan University of Medical Science, Shahid Fahmideh street, Hamadan

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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

**Street address**

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

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Mahshid Nikooseresht

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## Person responsible for updating data

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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