

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of lower limb bandaging to prevent hypotension caused by spinal anesthesia in patients undergoing caesarean section

Protocol summary

Study aim

Determining the effect of using bandaging in the lower limbs to prevent hypotension caused by spinal anesthesia in patients undergoing cesarean surgery.

Design

Tow arms parallel group randomized clinical trial on 90 patients. Random allocation of samples is done by block method (Blocks of 6).

Settings and conduct

This clinical trial study will be conducted on 90 patients undergoing cesarean section (in two intervention groups and one control group) in Ayatollah Mousavi Hospital, Zanjan. Random allocation of samples will be done in block method. A bedside monitor (Saadat Company, model 1800s) will be used to measure blood pressure and heart rate. Demographic information will be collected through the demographic information form. Blood pressure and heart rate will be measured and recorded every 2 minutes to 15 minutes, every 5 minutes to 30 minutes, and then every 10 minutes until the end of the surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 46 years; Candidate for elective caesarean section under spinal anesthesia; American Society of Anesthesiologists (ASA) Class I & II
Non inclusion criteria: The presence of contraindications to spinal anesthesia (patient refusal, coagulation disorder, high ICP, infection or abscess at the injection site); History of DVT (Deep Venous Thrombosis)

Intervention groups

Intervention group 1: Bandage below the knee will be done with bande No.10 Bandhaye Pezeshki Iran (Tebbi Shafa). Intervention group 2: Bandage up to the middle of the femur will be done with bande No.10 Bandhaye Pezeshki Iran (Tebbi Shafa). Control group: Will not receive any intervention.

Main outcome variables

Blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100220003379N4**

Registration date: **2023-03-17, 1401/12/26**

Registration timing: **prospective**

Last update: **2023-03-17, 1401/12/26**

Update count: **0**

Registration date

2023-03-17, 1401/12/26

Registrant information

Name

Mehdi Ghaemi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 1728 9915

Email address

mahiar@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-08-06, 1402/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of lower limb bandaging to prevent hypotension caused by spinal anesthesia in patients undergoing caesarean section

Public title

Investigating the effect of leg bandaging in the prevention of blood pressure reduction in cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 46 years Candidate for elective caesarean section under spinal anesthesia American Society of Anesthesiologists (ASA) Class I & II

Exclusion criteria:

The presence of contraindications to spinal anesthesia (patient refusal, coagulation disorder, high ICP, infection or abscess at the injection site) History of DVT (Deep Venous Thrombosis)

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be assigned to the three study groups by blocking the classification method. Blocks will be randomly selected with a size of 6. In each block (card), two patients are considered for intervention 1 (A), two patients for intervention 2 (B) and two patients for placement in the control group. For example (AACCB). In the next step, 15 cards will be selected from among the cards by a simple random method with placement. Based on this, the qualified patient will be placed in one of the study groups (intervention 1, 2 or control).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanzan University of Medical Sciences

Street address

Vice-Chancellor for Research and Technology, Zanzan University of Medical Sciences , Azadi Square, Zanzan, Iran.

City

Zanzan

Province

Zanzan

Postal code

4515613191

Approval date

2023-01-03, 1401/10/13

Ethics committee reference number

IR.ZUMS.REC.1401.285

Health conditions studied

1

Description of health condition studied

cesarean section

ICD-10 code

O75.82

ICD-10 code description

Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks gestation, with delivery by (planned) cesarean section

Primary outcomes

1

Description

Blood pressure

Timepoint

Every 2 minutes to 15 minutes, every 5 minutes to 30 minutes, and then every 10 minutes until the end of the surgery

Method of measurement

Bedside monitor (Saadat company model s1800)

Secondary outcomes

1

Description

Heart rate

Timepoint

Every 2 minutes to 15 minutes, every 5 minutes to 30 minutes, and then every 10 minutes until the end of surgery

Method of measurement

Bedside monitor (Saadat company, 1800s model)

Intervention groups

1

Description

Control group: Will not receive any intervention.

Category

N/A

2

Description

Intervention group 1: Bandage below the knee will be done with bande No.10 Bandhaye Pezeshki Iran (Tebbi Shafa).

Category

Treatment - Devices

3

Description

Intervention group 2: Bandage up to the middle of the femur will be done with bande No.10 Bandhaye Pezeshki Iran (Tebbi Shafa).

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi hospital

Full name of responsible person

Mehdi Ghaemi

Street address

Gavazang Road, Ayatollah Mousavi Hospital, Zanjan, Iran.

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4513956184

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Samad Nadri

Street address

Vice-Chancellor for Research and Technology, Zanjan University of Medical Sciences , Azadi Square, Zanjan, Iran.

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research@zums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Mehdi Ghaemi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

-

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Mehdi Ghaemi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work