

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of the effect of leg wrapping with elastic bandage for the prevention of Post spinal hypotension in cesarean section : A randomized clinical trial

Protocol summary

Study aim

Determining the effect of leg wrapping with elastic bandage for prevention of post spinal hypotension in cesarean section

Design

In this clinical trial, with Phase 2-3, 64 patients 18-46 years and candidate for cesarean section are randomly placed in two groups: using elastic bandages in the lower limbs and the control group.

Settings and conduct

In 32 of the 64 patients, candidates for cesarean section under spinal anesthesia in Fatemeh Hospital of Hamadan, immediately before spinal anesthesia, lower limbs are high held for 1 minute at a 45-degree, then elastic bandages are tied from ankles to the knees while in 32 patients of control group (without the use of bandages) they are subjected to spinal anesthesia

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 to 46 years; term pregnancy (37 weeks and more); Physical Status (ASA) Class 1 and 2; Candidate for cesarean section under spinal anesthesia; Satisfaction to participate in the research Exclusion criteria: respiratory disease; Hypertension; Diabetes; Heart failure and cardiac arrhythmia; Multiple pregnancies; Eclampsia and preeclampsia; Emergency cesarean section

Intervention groups

Patients are randomly assigned to Group A (lower limbs bandage) and B group (without lower limbs bandage).

Main outcome variables

Hypotension

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120915010841N23**

Registration date: **2020-06-29, 1399/04/09**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-29, 1399/04/09**

Update count: **0**

Registration date

2020-06-29, 1399/04/09

Registrant information

Name

Nahid Manouchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of leg wrapping with elastic bandage for the prevention of Post spinal hypotension in

cesarean section : A randomized clinical trial

Public title

Evaluation of the effect of elastic bandage on Post spinal hypotension

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 18 to 46 years With term pregnancy (37 weeks and more) Physical Status (ASA) Class 1 and 2 Candidate for cesarean section under spinal anesthesia Satisfaction to participate in the research

Exclusion criteria:

Patients with respiratory disease Hypertension Diabetes Heart failure and cardiac arrhythmia Multiple pregnancies Eclampsia and preeclampsia Emergency cesarean section

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

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 elastic bandage and control groups, 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)

Single blinded

Blinding description

In group A, immediately before spinal anesthesia, each lower limb is covered by an elastic bandage and covered by clothes. Since the bandage is performed by an anesthesiologist, the assistant who will measure and record the study result will not know if the bandage has been performed or not.

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

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Postal code

6517838678

Approval date

2020-06-13, 1399/03/24

Ethics committee reference number

IR.UMSHA.REC.1399.297

Health conditions studied**1****Description of health condition studied**

Post spinal anesthesia hypotension in C/S

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Hypotension

Timepoint

Every two minutes to 10 minutes, then every 5 minutes to 15minutes, then every 10 minutes until the end of the surgery

Method of measurement

Automatic non-invasive blood pressure device

Secondary outcomes**1****Description**

Systolic and Diastolic Blood Pressure

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

En Automatic non-invasive blood pressure device

2

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

3

Description

Nausea and Vomiting

Timepoint

During and after surgery

Method of measurement

Observation

4

Description

New born Apgar

Timepoint

1&5 minutes after delivery

Method of measurement

Apgar Score

5

Description

The amount of ephedrine have been consumed

Timepoint

During surgery

Method of measurement

mg

6

Description

The amount of atropine have been consumed

Timepoint

During surgery

Method of measurement

mg

Intervention groups

1

Description

Intervention group: Immediately before the spinal anesthesia, first lower limbs are high held for 1 minute at a 45-degree for venous derenage, second elastic bandages(a length of 4 meters and a width of 15 centimeters) are tied from ankles to the knees and limbs will be covered by clothes.

Category

Prevention

2

Description

Control group: They are subjected to spinal anesthesia without the use of elastic bandages

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Nahid Manouchehrian

Street address

Fatemieh 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

Latest degree

Specialist

Other areas of specialty/work

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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