

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Effect of one and two minutes sitting position versus immediate trendelenburg position after spinal anesthesia on hemodynamic variables in patients who undergo elective cesarean section: a double blinded randomized controlled trial

Protocol summary

Summary

Objectives: To assess the effect of one and two minutes sitting position versus immediate trendelenburg position after spinal anesthesia on hemodynamic variables in patients who undergo elective cesarean section. Design: a double blinded randomized clinical trial. Setting and conduct: All eligible patients who are candidate for elective cesarean section who will refer to the Fatemieh Hospital during the study period will be enrolled in to the trial. Inclusion criteria: (a); candidate for elective cesarean section; (b) age of 14 to 45 years; (c) gestational age more than 36 weeks. Exclusion criteria: (a) having gestational blood pressure; (b) having diabetes. Intervention: (a) one min sitting position after spinal anesthesia with hyperbaric bupivacaine 0.5%; (b) two min sitting position after spinal anesthesia with hyperbaric bupivacaine 0.5%. Control: immediate trendelenburg position after spinal anesthesia with hyperbaric bupivacaine 0.5%. Primary outcome: (a) assessing systolic and diastolic blood pressure using automatic monitoring machine before surgery and at 1, 2, 3, 5 min after beginning of surgery and then every 5 min till 30 min after beginning of surgery and then every 10 min to the end of surgery; (b) measuring arterial oxygen saturation using pulse oximetry before, during and 30 min after surgery. Secondary outcome: assessing systemic reaction such as nausea, vomiting, shivering, itching, short breath, and vertigo during and 30 min after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409299014N42**

Registration date: **2014-10-27, 1393/08/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-10-27, 1393/08/05

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-10-22, 1393/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of one and two minutes sitting position versus immediate trendelenburg position after spinal anesthesia on hemodynamic variables in patients who undergo elective cesarean section: a double blinded randomized controlled trial

Public title

Effect of one and two minutes sitting position versus immediate trendelenburg position after spinal anesthesia on hemodynamic variables in patients who undergo elective cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a); candidate for elective cesarean section; (b) age of 14 to 45 years; (c) gestational age more than 36 weeks. Exclusion criteria: (a) having gestational blood pressure; (b) having diabetes.

Age

From **14 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **65**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to the groups of intervention 1 and 2 and control group three paper sheets labeled A, B, and C. Blinding: The physician who will examine the patients will be unaware of the intervention. The analyzer will also unaware of intervention. Therefore, the trial will be run as double blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid

Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2014-05-17, 1393/02/27

Ethics committee reference number

D/P/16/35/9/698

Health conditions studied

1

Description of health condition studied

elective cesarean section

ICD-10 code

O26.9

ICD-10 code description

Pregnancy-related condition, unspecified

Primary outcomes

1

Description

assessing systolic and diastolic blood pressure

Timepoint

before surgery and at 1, 2, 3, 5 min after beginning of surgery and then every 5 min till 30 min after beginning of surgery and then every 10 min to the end of surgery

Method of measurement

using automatic monitoring machine

2

Description

measuring arterial oxygen saturation

Timepoint

before, during and 30 min after surgery

Method of measurement

using pulse oximetry

Secondary outcomes

1

Description

assessing systemic local reaction such as nausea, vomiting, shivering, itching, short breath, and vertigo

Timepoint

during and 30 min after surgery

Method of measurement

through physical examination and question

Intervention groups

1

Description

one min sitting position after spinal anesthesia with

hyperbaric bupivacaine 0.5%

Category

Treatment - Other

2

Description

two min sitting position after spinal anesthesia with hyperbaric bupivacaine 0.5%

Category

Treatment - Other

3

Description

immediate trendelenburg position after spinal anesthesia with hyperbaric bupivacaine 0.5%

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Taiebeh Lotfi

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Fatemieh Hospital

Full name of responsible person

Taiebeh Lotfi

Position

Medical student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Dr Pooran Hajian

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00

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p_hajian48@yahoo.com

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty