Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the hemodynamic effects of the patient position (sitting, right and left lateral position) during induction of spinal anesthesia for caesarean section: a randomized clinical trial

Protocol summary

Study aim

To assess the hemodynamic effects of the patient position (sitting, right and left lateral position) during induction of spinal anesthesia for caesarean section

Design

This is a randomized clinical trial, in which eligible patients will be randomly assigned through the block randomization to the intervention groups.

Settings and conduct

This study will be performed in the Fatemieh Hospital in Hamadan city on 105 pregnant women candidate for cesarean section. The patients will be randomly assigned through the block randomization to the intervention groups. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 40 years; Pregnant women candidate for cesarean section; Exclusion criteria: Multipara; Cardiovascular disease or diabetes or preeclampsia; Coagulopathy

Intervention groups

Intervention group 1: Spinal anesthesia for cesarean section in a sitting position with spinal injection of 10 mg bupivacaine hyperbaric 5% plus 2.5 µg sufentanil Intervention group 2: Spinal anesthesia for cesarean section lying down on the right side with spinal injection of 10 mg bupivacaine hyperbaric 5% plus 2.5 micrograms sufentanil Intervention group 3: Spinal anesthesia for cesarean section lying down on the left side with spinal injection of 10 mg bupivacaine hyperbaric 5% plus 2.5 µg sufentanil

Main outcome variables

Primary outcome: Blood pressure, heart rate Secondary outcome Side effects (nausea, vomiting and chilling), neonatal Apgar score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N412**
Registration date: **2021-12-11, 1400/09/20**
Registration timing: **prospective**

Last update: **2021-12-11, 1400/09/20**
Update count: **0**

Registration date

2021-12-11, 1400/09/20

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

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the hemodynamic effects of the patient position (sitting, right and left lateral position) during induction of spinal anesthesia for caesarean section: a randomized clinical trial

Public title
Comparison of the hemodynamic effects of the patient position (sitting, right and left lateral position) during induction of spinal anesthesia for caesarean section

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 40 years; Pregnant women candidate for cesarean section;
Exclusion criteria:
Multipara; Cardiovascular disease or diabetes or preeclampsia; Coagulopathy

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on two sheets the name of the intervention 1 and on two other sheets the name of the intervention 2 and on the third two sheets the name of the intervention 3. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

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 Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695

Approval date
2020-01-11, 1398/10/21

Ethics committee reference number
IR.UMSHA.REC.1398.871

Health conditions studied

1

Description of health condition studied
Cesarean section

ICD-10 code
Z38.01

ICD-10 code description
Single liveborn infant, delivered by cesarean

Primary outcomes

1

Description
Blood pressure

Timepoint
At 1, 2, 3, 4, 5, 10, 15 and 20 minutes after spinal anesthesia

Method of measurement
With a monitor

2

Description
Heart rate

Timepoint
At 1, 2, 3, 4, 5, 10, 15 and 20 minutes after spinal anesthesia

Method of measurement
With a monitor

Secondary outcomes

1

Description
Side effects (nausea, vomiting and chilling)

Timepoint
20 minutes after spinal anesthesia

Method of measurement
With history taking

2

Description
Neonatal Apgar score
Timepoint
At 1 and 5 minutes after cesarean section
Method of measurement
With clinical examination

Intervention groups

1

Description
Intervention group 1: Spinal anesthesia for cesarean section in a sitting position with spinal injection of 10 mg bupivacaine hyperbaric 5% plus 2.5 µg sufentanil
Category
Treatment - Other

2

Description
Intervention group 2: Spinal anesthesia for cesarean section lying down on the right side with spinal injection of 10 mg bupivacaine hyperbaric 5% plus 2.5 micrograms sufentanil
Category
Treatment - Other

3

Description
Intervention group 3: Spinal anesthesia for cesarean section lying down on the left side with spinal injection of 10 mg bupivacaine hyperbaric 5% plus 2.5 µg sufentanil
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital in Hamadan city
Full name of responsible person
Mitra Garousi
Street address
Fatemieh Hospital, Pasdaran Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
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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
Mitra Garousi
Position
Medical Student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

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Person responsible for updating data

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Professor of Epidemiology

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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