# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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
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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
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Fatemieh Hospital, Pasdaran Ave.
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## Sponsors / Funding sources

**1**

**Sponsor**
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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
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Mitra Garousi
**Position**
Medical Student
**Latest degree**
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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