# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

04 Aug 2026

## Comparing the effects of bupivacaine and ropivacaine on the patients undergoing cesarean section in spinal anesthesia

### Protocol summary

**Study aim**
Comparing the effects of bupivacaine and ropivacaine on patients undergoing cesarean section in spinal anesthesia

**Design**
A double-blind randomized clinical trial with parallel groups and 60 patients (30 people in each group).

**Settings and conduct**
60 patients undergoing elective cesarean section with anesthesia risk (ASA I-II) in Imam Khomeini Hospital will be randomly divided into two groups of 30 patients: group1 receiving ropivacaine 1%( 15mg) and group 2 receiving hyperbaric bupivacaine 0.5% (10 mg). Spinal anesthesia will be performed in sitting position in the L3-L4 or L4-L5 space using the spinal needle. The patient's blood pressure will be measured every five minutes. Sensory and motor evaluation will be performed every 5 minutes in the first 32 minutes and then at 12-minute intervals until the end of surgery. The pain score of patients will be measured at the beginning and end of the surgery and at the time of discharge from the recovery room. Postoperative clinical complications of patients will be evaluated until 24 hours after surgery.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Term pregnancy (over 37 and less than 42 weeks), elective cesarean section, 20-40 years, weight between 65 and 95 kg, height between 155 and 175 cm, ASA Class I - II. Exclusion criteria: Preterm and post term, abnormalities and problems of placenta or fetus, allergy to local anesthetics, spinal anesthesia contraindications.

**Intervention groups**
Patients were randomly divided into two groups receiving bupivacaine and ropivacaine. Group1: ropivacaine 1%( 15mg) was injected during surgery Group2: hyperbaric bupivacaine 0.5% (10 mg)was injected during surgery.

**Main outcome variables**
Sensory and motor block duration; blood pressure; heart rate; pain score; postoperative clinical complications

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190529043751N1**
Registration date: **2019-07-08, 1398/04/17**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-08, 1398/04/17**
Update count: **0**

**Registration date**
2019-07-08, 1398/04/17

**Registrant information**

**Name**
Raziyeh Homayoon

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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+98 61 3221 1492

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-04-04, 1398/01/15

**Expected recruitment end date**
2019-12-21, 1398/09/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

Comparing the effects of bupivacaine and ropivacaine on the patients undergoing cesarean section in spinal anesthesia

**Public title**
Comparing the effects of bupivacaine and ropivacaine in the casarean section.
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Term pregnancy (over 37 and less than 42 weeks) Elective cesarean section 20-40 years Weight between 65 and 95 kg Height between 155 and 175 cm ASA class I,II
**Exclusion criteria:**
Preterm and post term Abnormalities and problems of placenta or fetus Allergy to local anesthetics Spinal anesthesia contraindications
**Age**
From **20 years** old to **40 years** old
**Gender**
Female

**Phase**
2
**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
By random block permutation, individuals will be randomly divided into two groups. The block sizes can be 4, 6 and so on. 6 blocks including 4 characters will be considered; AABB, ABAB, BBAA, BABA, ABBA, and BAAB. We will sample from the six blocks, with replacement to the extent that the sample size is completed. In this case, a sequence of letters will be obtained, in which individuals will be randomly divided into two equal groups.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
All medications will be in similar and dark pockets. A numeric label will be on each pack of medications. Patient and researcher will not inform of the number assigned to the relevant group. Then, according to the random sequence based on random block permutation, the packets of medications will be given to the researcher.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
**Street address**
Jundishapur University of Medical Sciences, Golestan Blvd., Golestan Town
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
61357-15794
**Approval date**
2019-03-02, 1397/12/11
**Ethics committee reference number**
IR.AJUMS.REC.1397.903

## Health conditions studied

### 1

**Description of health condition studied**
cesarean
**ICD-10 code**
O74
**ICD-10 code description**
Complications of anesthesia during labor and delivery

## Primary outcomes

### 1

**Description**
Motor block duration
**Timepoint**
Every 5 minutes in the first 32 minutes and then at 12-minute intervals until the end of surgery.
**Method of measurement**
Modified bromage scale

### 2

**Description**
Ṡensory block duration
**Timepoint**
Every 5 minutes in the first 32 minutes and then at 12-minute intervals until the end of surgery.
**Method of measurement**
pin prick

## Secondary outcomes

### 1

**Description**
Blood pressure

**Timepoint**
Every 5 minutes before injection until delivery and then every 15 minutes until discharge from the recovery room.
**Method of measurement**
Non-invasive Blood Pressure (NIBP)

**2**

**Description**
Heart rate
**Timepoint**
Every 5 minutes before injection until delivery and then every 15 minutes until discharge from the recovery room.
**Method of measurement**
ECG

**3**

**Description**
Analgesia
**Timepoint**
In the beginning and end of surgery and, when discharging from recovery room
**Method of measurement**
Visual analogues Scale

**4**

**Description**
Postoperative Clinical complications
**Timepoint**
Until 24 hours after discharge from the recovery room
**Method of measurement**
Examination

## Intervention groups

**1**

**Description**
Ropivacaine group: Ropivacaine 1%( 15mg) ) (manufactured by Dei Fratelli Societa Di Eserciozio SpA C & Molteni L, Italy) will be injected during surgery.
**Category**
Treatment - Drugs

**2**

**Description**
Bupivacaine group: Hyperbaric bupivacaine 0.5% (10 mg)(manufactured by AstraZeneca, Sweden) will be injected during surgery.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Imam Khomeini hospital
**Full name of responsible person**
Raziyeh Homayoon
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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**
Ahvaz 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**
Ahvaz University of Medical Sciences
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Raziyeh Homayoon
**Position**
Assistant
**Latest degree**
Medical doctor
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
To keep patients' information confidential
**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