

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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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

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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

Sensory 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 Esercizio 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****Name of organization / entity**

Ahvaz 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

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

Full name of responsible person

Raziyeh Homayoon

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Reza Akhondzadeh

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Assistant Professor

Latest degree

Specialist

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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