

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparison of dose divided by bolus injection of bupivacaine in spinal anesthesia in patients undergoing cesarean section

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Study aim

Comparison of dose divided by bolus injection of bupivacaine in spinal anesthesia

Last update: **2019-12-25, 1398/10/04**

Update count: **0**

#### Design

This randomized double-blind clinical trial will be performed on 60 patients undergoing cesarean section in the control group marcaein will be administrate as a bolus dose and in intervention group marcaein will be administrate as divided dose.

#### Registration date

2019-12-25, 1398/10/04

#### Registrant information

##### Name

sima rousta

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3374 3017

##### Email address

rousta.s@ajums.ac.ir

#### Settings and conduct

The study will be conducted at Imam Khomeini Hospital in Ahvaz. Patients will be randomly divided into control and experimental groups. Patients in the control group received bolus bupivacaine for 12 seconds. In the patients in the intervention group, the administration of bupivacaine is divided. The participants, the principal researcher, are ward nurses with respect to the study

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

inclusion Candidate for elective cesarean section  
Anesthesia Class (I-II) Age 18 to 40 years Satisfied with spinal anesthesia  
Exclusion Hypertension caused by pregnancy, cardiovascular disease or mental illness  
Contraindication to spinal anesthesia History of laminectomy

#### Expected recruitment start date

2019-10-23, 1398/08/01

#### Expected recruitment end date

2019-12-31, 1398/10/10

#### Intervention groups

Administration of marcaein in the intrathecal space by divided does method in the intervention group  
Administration of marcaein in the Intrathecal Space by the bolus method in the Control Group

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Main outcome variables

Sensory block; motor block; pain

#### Trial completion date

empty

#### General information

#### Scientific title

Comparison of dose divided by bolus injection of bupivacaine in spinal anesthesia in patients undergoing cesarean section

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20191001044941N1**

Registration date: **2019-12-25, 1398/10/04**

#### Public title

Comparison of divided doses with bolus injection of bupivacaine in spinal anesthesia

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Candidate for elective cesarean section Anesthesia Class (I-II) Age 18 to 40 years Satisfied with spinal anesthesia

### Exclusion criteria:

Pregnancy hypertension Cardiovascular disease or mental illness Contraindication to spinal anesthesia Forward weighing less than 50 kg and more than 110 kg Having a history of laminectomy

## Age

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

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

According to the random number table, they will be divided into two groups of 30 people

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The principal investigator (supervisor) performs spinal anesthesia and is in the process of blinding, but the patient and physician sampled and the recovery nurse assessing the block and pain are not aware of the type and mode of spinal anesthesia.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ahwaz Jundishapour University of Medical Sciences

##### Street address

Ahwaz Jundishapour University of Medical science;research deputy;Blvd.golestan

##### City

Ahwaz

## Province

Khouzestan

## Postal code

6135715794

## Approval date

2019-10-06, 1398/07/14

## Ethics committee reference number

IR.AJUMS.REC.1398.497

## Health conditions studied

### 1

#### Description of health condition studied

pain

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Sensory block

#### Timepoint

Measurement of sensory block at baseline and one and two hours after surgery

#### Method of measurement

Visual Analogue Scale

### 2

#### Description

Motor block

#### Timepoint

Measurement of motor block at baseline and one and two hours after surge

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

pain intensity

#### Timepoint

0-1-2Hours after cesarean section

#### Method of measurement

visual analoge scale

## Intervention groups

### 1

#### Description

Intervention group: bupivacaine, 0.5%, 12 mg, in divided doses ,for 1/3 full dose is administered initially and after 60 seconds the remaining 2/3 is injected.

#### Category

Treatment - Drugs

**2**

**Description**

Control group: Administration of bupivacaine 12 mg as a bolus

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Kaveh Behaeen

**Street address**

Imam khomeinin,Azadedegan Ave

**City**

Ahwaz

**Province**

Khuzestan

**Postal code**

6193673166

**Phone**

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srousta2000@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Badavi

**Street address**

Deputy of Research,Ahwaz JondishapoorUniversity of Medical Sciences,Golestan Blvd

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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**

kaveh Behaeen

**Position**

Consultan

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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behaeen@yaho0.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

kaveh Behaeen

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

kaveh Behaeen

**Position**

Consultant

**Latest degree**

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Anesthesiology

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**Postal code**

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**Phone**

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### Email

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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