

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparison of the Effects of Ropivacaine 0.2% and Bupivacaine 0.5% on Hemodynamic Heart Consequences in Cesarean Section Using Epidural Anesthesia in Besat Hospital, Sanandaj, Iran

#### Protocol summary

##### Study aim

Comparison of the Effects of Ropivacaine 0.2% and Bupivacaine 0.5% on Hemodynamic Heart Consequences in Cesarean Section Using Epidural Anesthesia

##### Design

Two intervention groups of 61 people, parallel, double-blind, randomized

##### Settings and conduct

Pregnant women who are candidates for elective cesarean section are randomly divided into two groups of 61 patients. Medication stickers are separated by a statistical adviser and they will be coded. Then injected into patients. Participants in the study and researcher and information collector and clinical observer are blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include pregnant women aged 20 to 35 years, an indication of elective cesarean section with epidural anesthesia, informed consent of patients and the possibility of epidural anesthesia. Exclusion criteria include underlying illnesses such as blood pressure, diabetes, heart disease, coagulation disorder; pregnancy complications such as placental abruption, preeclampsia, fetal distress, IUGR, Allergy to local anesthetics, Alcoholism and drug Addiction and Local infection.

##### Intervention groups

The first intervention group is a group of patients who Will be anesthetized with 20 ml of ropivacaine 0.2% with epidural anesthesia. The second intervention group is a group of patients who Will be anesthetized with 20 ml of bupivacaine 0.5% with epidural anesthesia.

##### Main outcome variables

The incidence of hypotension (less than 20% of the baseline); the incidence of bradycardia (less than 60)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181022041413N1**  
Registration date: **2019-01-23, 1397/11/03**  
Registration timing: **retrospective**

Last update: **2019-01-23, 1397/11/03**

Update count: **0**

##### Registration date

2019-01-23, 1397/11/03

##### Registrant information

##### Name

Behzad Ahsan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3323 1805

##### Email address

sinasoltanian@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-17, 1397/07/25

##### Expected recruitment end date

2018-12-15, 1397/09/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Effects of Ropivacaine 0.2% and

Bupivacaine 0.5% on Hemodynamic Heart Consequences in Cesarean Section Using Epidural Anesthesia in Besat Hospital, Sanandaj, Iran

#### Public title

Comparison of the Effects of Ropivacaine 0.2% and Bupivacaine 0.5% on Hemodynamic Heart Consequences in Cesarean Section Using Epidural Anesthesia

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Pregnant women 20 to 35 years old Indication for elective cesarean section with epidural anesthesia Informed consent Possibility of epidural anesthesia

##### Exclusion criteria:

Underlying disease like hypertension, diabetes, heart disease, coagulation disorders Pregnancy complications such as placental abruption, preeclampsia, fetal distress, IUGR Allergy to local anesthetics Alcoholism and drug Addiction Local infection

#### Age

From **20 years** old to **35 years** old

#### Gender

Female

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator

#### Sample size

Target sample size: **122**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomization is done based on throwing coins. And from the number 1 to 122, the coin is thrown. And based on throwing coins, they are placed in the ropivacaine or bupivacaine group.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Randomization and blindness is done by a statistic consultant. And the label of the vial of medications is taken. And are numbered from 1 to 122. According to the number of patients entering the study, each number is assigned to one person. Participants in the study and researcher and information collector and clinical observer are blind. And they are not aware of the drug inside the vial.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

###### Street address

Kurdistan University of Medical Sciences, Pasdaran Blv

###### City

Sanandaj

###### Province

Kurdistan

###### Postal code

666147 - 13446

##### Approval date

2018-10-17, 1397/07/25

##### Ethics committee reference number

IR.MUK.REC.1397.182

### Health conditions studied

#### 1

##### Description of health condition studied

Elective cesarean section

##### ICD-10 code

##### ICD-10 code description

Elective cesarean section

### Primary outcomes

#### 1

##### Description

Incidence rate of hypotension during epidural anesthesia: If the blood pressure is less than 20% of the basic rate, defined hypotension

##### Timepoint

Blood pressure will be measure and record at the time before the anesthesia and do 5 minutes and 10 minutes 15 minutes 20 minutes and 35 minutes and 50 minutes and 65 minutes after anesthesia

##### Method of measurement

Sphygmomanometer

### Secondary outcomes

#### 1

##### Description

Incidence rate of bradycardia during epidural anesthesia: If the pulse rate is less than 60, defined bradycardia

##### Timepoint

Pulse rate will be measure and record at the time before the anesthesia and do 5 minutes and 10 minutes 15 minutes 20 minutes and 35 minutes and 50 minutes and 65 minutes after anesthesia

##### Method of measurement

Cardiac monitoring

## Intervention groups

### 1

#### Description

Intervention group: The first intervention group: 61 patients receiving 20 ml of ropivacaine 0.2% once for epidural anesthesia.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Second intervention group: 61 patients receiving 20 ml of bupivacaine 0.5 once once for epidural anesthesia.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat hospital

##### Full name of responsible person

Behzad Ahsan

##### Street address

Pasdarán Blv, Kurdistan University of Medical Sciences

##### City

Sanandaj

##### Province

Kurdistan

##### Postal code

666147 - 13446

##### Phone

+98 87 3323 1805

##### Email

sinasoltanian@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sanandaj University of Medical Sciences

##### Full name of responsible person

Ebrahim Ghaderi

##### Street address

Kurdistan University of Medical Sciences, Pasdarán Blv

##### City

Sanandaj

##### Province

Kurdistan

##### Postal code

13446-666147

##### Phone

+98 87 3182 7272

##### Email

ebrahimghaderi@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

##### Full name of responsible person

Sina Soltanian

##### Position

Medical student

##### Latest degree

Medical doctor

##### Other areas of specialty/work

General Practitioner

##### Street address

Kurdistan University of Medical Sciences, Pasdarán Blv

##### City

Sanandaj

##### Province

Kurdistan

##### Postal code

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##### Phone

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##### Email

sinasoltanian@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Sanandaj University of Medical Sciences

##### Full name of responsible person

Behzad Ahsan

##### Position

Associate professor

##### Latest degree

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

No. 21, Shaghayegh 4 Alley, Takiyeh va chaman st.,  
Abidar Blv, sanandaj

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behzadahsan@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Behzad ahsan

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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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