

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Effects of Ropivacine 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 Ropivacine 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 Ropivacine 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 Ropivacine 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, Pasharan 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

Pasdaran 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, Pasdaran 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, Pasdaran Blv

City

Sanandaj

Province

Kurdistan

Postal code

13446-666147

Phone

+98 87 3182 7272

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

City

Sanandaj

Province

Kurdistan

Postal code

66188-44761

Phone

+98 87 3323 1805

Email

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

Street address

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

City

Sanandaj

Province

Kurdistan

Postal code

66188-44761

Phone

+98 87 3323 1805

Email

behzadahsan@gmail.com

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