Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of single-shot epidural and spinal anesthesia in elective caesarean section in terms of hemodynamic changes and surgeon satisfaction.

Protocol summary

Study aim

Comparison of single-shot epidural and spinal anesthesia in elective caesarean section in terms of hemodynamic changes and surgeon satisfaction.

Design

The present study is a parallel, single-blind randomized clinical trial. A total of 80 patients will be enrolled in the study. Eligible patients will be randomly assigned to two equal groups, A and B, using a block randomization method.

Settings and conduct

Patients who present to Ghadir Mother and Child Hospital in Shiraz during the study will be enrolled if they meet the eligibility criteria. They will be randomly assigned to intervention and control groups using a block randomization method. This study will be conducted as a single-blind trial.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women aged 18 to 44 years with ASA class I and women undergoing elective cesarean section under spinal anesthesia. Exclusion Criteria: Emergency cesarean section, hemodynamic instability, history of substance abuse and addiction, fetal distress, and altered level of consciousness due to eclampsia.

Intervention groups

Control group: after the necessary pre-operative assessments, is positioned seated. Using a 27-gauge spinal needle and the median approach at the L3-L4 space, 10 mg of 5% Marcaine and 10 micrograms of fentanyl are injected into the cerebrospinal fluid. targeting a desired level of T4 anesthesia. Intervention group: after the necessary pre-operative assessments, epidural anesthesia is performed using an 18-gauge Tuohy needle at the midline with the loss of resistance technique in the L3-L4 or L4-L5 space. If the epidural space is confirmed and no intravascular injection is detected, 16 cc of 0.5% Marcaine along with 100 micrograms of fentanyl is injected into the epidural space. The goal of this injection is to achieve the desired anesthesia level at T4.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091117002723N5**
Registration date: **2024-11-12, 1403/08/22**
Registration timing: **prospective**

Last update: **2024-11-12, 1403/08/22**
Update count: **0**

Registration date

2024-11-12, 1403/08/22

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

07112337636

Email address

hadavimr@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-01, 1403/09/11

Expected recruitment end date

2025-09-01, 1404/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of single-shot epidural and spinal anesthesia in elective caesarean section in terms of hemodynamic changes and surgeon satisfaction.

Public title

Comparison of Two Anesthesia Methods in Cesarean Section: Epidural and Spinal

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult women with ASA grade I (American Society of Anesthesiology classification) Women having elective caesarean section under spinal anesthesia Women between 18 and 44 years old

Exclusion criteria:

Adult women with ASA grade II, III or IV (American Society of Anesthesiology classification) Emergency caesarean section Pregnancy Induced Hypertension Hemodynamic instability Multiple pregnancy History of drug use and addiction Fetal distress Eclamptic level of consciousness disorder (seizures, pulmonary edema, headache, visual disturbances)

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocated into two groups by block randomization. In this technique, a permutation block of size 8 will be made for patients of two groups A & B. In each block, equal numbers for two groups will be considered in alternative positions. Then 10 blocks of size 8 will be selected randomly and patients will be allocated randomly and equally into two groups according to these permutation block. block sequence will be prepare by www.sealedenvelope.com.

Blinding (investigator's opinion)

Single blinded

Blinding description

Before performing the anesthesia block, informed consent will be obtained from all patients, and they will be fully informed about the type of anesthesia to be used. In this study, an independent anesthesiologist, who is unaware of the randomization and type of anesthesia, will only assess and record the variables under investigation. This study is designed as a single-blind study to enhance the objectivity and accuracy of the results.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz Medical School

Street address

3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2024-09-09, 1403/06/19

Ethics committee reference number

IR.SUMS.MED.REC.1403.390

Health conditions studied

1

Description of health condition studied

Cesarean section

ICD-10 code

O82

ICD-10 code description

Encounter for cesarean delivery without indication

Primary outcomes

1

Description

Pain

Timepoint

During operation and at 2, 4, 6, 12, 24 hours after surgery

Method of measurement

Questionnaire and Numerical Pain Rating Scale (NRS)

2

Description

Consent of the surgeon

Timepoint

At the end of surgery

Method of measurement

Score 8-10: very high satisfaction, the surgeon is satisfied with all aspects of the operation.6-7 score: high satisfaction, the surgeon is satisfied with most aspects of the operation. Score 4-5: average satisfaction, the surgeon is satisfied with some aspects of the operation.2-3 score: low satisfaction, the surgeon is dissatisfied with some aspects of the operation.0-1 score: very low satisfaction, the surgeon is dissatisfied with most or all aspects of the procedure.

3

Description

Heart rate

Timepoint

Prior to the commencement of anesthesia, during the surgical procedure, and subsequently at 2, 4, 6, 12, and 24 hours following the completion of the surgery.

Method of measurement

Monitoring

4

Description

Blood Pressure

Timepoint

Prior to the commencement of anesthesia, during the surgical procedure, and subsequently at 2, 4, 6, 12, and 24 hours following the completion of the surgery.

Method of measurement

Monitoring

Secondary outcomes

empty

Intervention groups

1

Description

Control group: The first group, after the necessary preparations and pre-operative assessments, is positioned seated. Using a 27-gauge spinal needle and the median approach at the L3-L4 space, 10 mg of 5% Marcaine and 10 micrograms of fentanyl are injected into the cerebrospinal fluid. Subsequently, the patient is transferred to a supine position, and the sensory block level is evaluated using a blunt needle, targeting a desired level of T4 anesthesia.

Category

Treatment - Surgery

2

Description

Intervention group: In the second group, after positioning the patient in a seated position and completing the necessary preparations and pre-operative assessments, epidural anesthesia is performed using an 18-gauge Tuohy needle at the midline with the loss of resistance technique in the L3-L4 or L4-L5 space. Following the confirmation of entry into the epidural space, a test dose consisting of 3 cc of lidocaine and 15 micrograms of epinephrine is injected. If the epidural space is confirmed and no intravascular injection is detected, 16 cc of 0.5% Marcaine along with 100 micrograms of fentanyl is injected into the epidural space. The goal of this injection is to achieve the desired anesthesia level at T4.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghadir Mother and Child Hospital

Full name of responsible person

Elnaz Rahimi

Street address

Ghadir Mother and Child Hospital, the beginning of Golshan town, above the Quran gate.

City

Shiraz

Province

Fars

Postal code

۷۱۴۴۹۹۵۴۷۷

Phone

+98 71 3227 9701

Fax

Email

Motherhosp@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad hashem Hashempour

Street address

7th floor, central building of Shiraz University of Medical Sciences, Vice Chancellor of research, Zand street.

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3235 7282

Email

hashempur@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Elnaz Rahimi

Position
Anesthesiology resident/physician

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
Anesthesiology Department, Faghihi Hospital, Zand Street.

City
Shiraz

Province
Fars

Postal code
7134844119

Phone
+98 71 3647 4270

Email
hasheminasabm@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Seyed Mohammad Reza Hadavi

Position
Assistant Professor of Pain Anesthesiology

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Anesthesiology Department, Faghihi Hospital, Zand Street

City
Shiraz

Province
Fars

Postal code
7134844119

Phone
+98 71 3647 4270

Email
hadavimr@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Hamide Saeedizade

Position
Research Assisstant

Latest degree
Bachelor

Other areas of specialty/work
Medical Informatics

Street address
Anesthesiology Department, Faghihi Hospital, Zand Street.

City
Shiraz

Province
Fars

Postal code
7134844119

Phone
0098-36281460

Email
saeedi.hamide@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