Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

Study aim
Comparison of dose divided by bolus injection of bupivacaine in spinal anesthesia
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.
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
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
Intervention groups
Administration of marcain in the intrathecal space by divided does method in the intervention group Administration of marcaine in the Intrathecal Space by the bolus method in the Control Group
Main outcome variables
Sensory block; motor block; pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191001044941N1**
Registration date: **2019-12-25, 1398/10/04**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-25, 1398/10/04**
Update count: **0**
Registration date
2019-12-25, 1398/10/04

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-10-23, 1398/08/01
Expected recruitment end date
2019-12-31, 1398/10/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

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

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 to40years 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
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Imam khomeinin,Azadedegan Ave
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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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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
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Position
Consultan
Latest degree
Specialist
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Person responsible for updating data

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Latest degree
Specialist

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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