Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Effect of adding lidocaine to Patient Controlled Analgesia (PCA) with morphine on pain intensity after cesarean section with spinal anesthesia

Protocol summary

Study aim
Evaluate the effect of adding lidocaine to Patient Controlled Analgesia (PCA) with morphine on pain intensity after Cesarean section with spinal anesthesia

Design
Two arm parallel group, double blind, randomised clinical trial of 80 patients between October 2018 to December 2018.

Settings and conduct
Before anesthesia, venous access in the forearm of the nondominant hand of patients are established. Thirty minutes before the procedure, 7ml /kg of crystalloid serum will given to these patients and then spinal anesthesia will be performed. Patients will be placed in the sitting position, and the spinal puncture will perform in the L3-L4 and L4-L5 level with mid-line approach. Then 10-15 mg of Bupivacaine 0.5% will be administered for the patient and the T4 sensory level will provided. After completion of anesthesia and patients' recovery, all patients will connected to a Patient-controlled analgesia (PCA) pump.

Participants/Inclusion and exclusion criteria
Preliminary selection of patients will be done according to inclusion and exclusion criteria.The inclusion criteria included candidates for non-emergency cesarean section with the spinal anesthesia. Patients with known sensitivity to lidocaine or bupivacaine will be excluded.

Intervention groups
For patients in the intervention group, the PCA solution contain 50 ml of 2% lidocaine with 30 mg (3 ml) of morphine in 47 mL of normal saline (total volume 100 ml). In the control group, the PCA solution contain 30 mg of morphine (3 ml) in 97 ml of normal saline. The PCA will be set to administer a bolus dose of 0.5 mL with a lockout interval of 15 minutes and a background infusion rate of 2 mL/h.

Main outcome variables
The pain intensity of the patients in the two groups after surgery will be evaluated using the visual analogue scale (VAS) at 2, 4, 6, 12, 18 and 24 hours after surgery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100713004365N23**
Registration date: **2018-09-22, 1397/06/31**
Registration timing: **prospective**

Last update: **2018-09-22, 1397/06/31**
Update count: **0**

Registration date
2018-09-22, 1397/06/31

Registrant information

Name
Afshin Gholipour Baradari

Name of organization / entity
Mazandaran University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-17, 1397/07/25

Expected recruitment end date
2018-12-31, 1397/10/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of adding lidocaine to Patient Controlled Analgesia (PCA) with morphine on pain intensity after cesarean section with spinal anesthesia

Public title
Effect of adding lidocaine to morphine for pain control after cesarean section

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The patient's willingness to participate in the study and obtain informed consent Candidate for non-emergency cesarean section with spinal anesthesia Age between 45 and 20 years Class I of American Society of Anaesthesiologists (ASA) physical status Body mass index (BMI) less than 40 Parity 1 or 2

Exclusion criteria:
Known sensitivity to lidocaine or bupivacaine History of previous intra abdominal surgery Multiple pregnancy Pre-operative acute pain History of substance abuse and psychotropic drugs consumption Unwillingness to perform spinal anesthesia

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Before the start of the study, the list of subjects for 2 groups of the study will be determined randomly, using a computer-generated random list for 80 patients. Based on this list, envelopes in which the name of one of the treatment groups is written are prepared. These envelopes are placed in the operating room, and if patients meet the inclusion criteria, an envelope will be opened for each patient and their treatment group will be identified accordingly. This work will be done by an anesthetist technician.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be double-blind, and the data analyser, collaborative nurses who will asses the outcomes of the study and patients are unaware of the patients' treatment groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences

Street address
Vice chancellor for research, Moallem Square, Mazandaran University of Medical Sciences, Sari, Mazandaran, Iran

City
Sari

Province
Mazandaran

Postal code
4815733971

Approval date
2017-04-04, 1396/01/15

Ethics committee reference number
IR.MAZUMS.REC.95.2528

Health conditions studied

1

Description of health condition studied
Cesarean section

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Pain intensity after surgery

Timepoint
2, 4, 6, 12, 18 and 24 hours after surgery

Method of measurement
Visual analogue scale

Secondary outcomes

1

Description
Satisfaction with pain control

Timepoint
24 hours after intervention

Method of measurement
Visual Analogue Scale

2

Description
Nausea
Timepoint
2, 4, 6, 12, 18 and 24 after surgery
Method of measurement
Visual Analogue Scale

3

Description
Length of hospital stay
Timepoint
Discharge from the hospital
Method of measurement
Patients record

4

Description
Amount of drug consumed through morphine pump
Timepoint
24 hours after intervention
Method of measurement
Patients record

5

Description
Return of normal bowel function
Timepoint
During the time of study
Method of measurement
Patients record

Intervention groups

1

Description
Intervention group: For patients in the intervention group, the PCA solution contain 50 ml of 2% lidocaine with 30 mg (3 ml) of morphine in 47 mL of normal saline (total volume 100 ml) which will be infused during the 24 hours. The PCA will be set to administer a bolus dose of 0.5 mL with a lockout interval of 15 minutes and a background infusion rate of 2 mL/h.
Category
Treatment - Drugs

2

Description
Control group: In the control group, the PCA solution contain 30 mg of morphine (3 ml) in 97 ml of normal saline which will be infused during the 24 hours. The PCA will be set to administer a bolus dose of 0.5 mL with a lockout interval of 15 minutes and a background infusion rate of 2 mL/h.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sari Imam khomeini hospital
Full name of responsible person
Afshin Gholipour Baradari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeedi
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Vice chancellor for research, Moallem Square, Mazandaran University of Medical Sciences, Sari, Mazandaran, Iran
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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
Sari 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
Mazandaran University of Medical Sciences
Full name of responsible person
Afshin Gholipour Baradari
Position
Professor
Latest degree
Subspecialist
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Anesthesiology
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Person responsible for updating data

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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