

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparsion of intraincisional bupivacaine, tramadol and bupivacaine plus tramadol in postoperative pain in elective cesarean section patients

Protocol summary

Study aim

Comparison of the effect of postoperative pain control and complications of bupivacaine, tramadol and a mixture of bupivacaine and tramadol by injection at the incision site in patients undergoing elective cesarean section

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 90 patients by permutation block method was used for randomization by random allocation method.

Settings and conduct

Participants in the study (n = 90) will be assigned to 3 groups A, B and C by permutation block method. Patients and evaluators do not know the type of treatment groups of participating patients. Place of study: Imam Khomeini Hospital Anesthesia group

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 15-45 years, having informed written consent to cooperate with the study, patient classification in ASA1-2 class. Exclusion criteria: Refusal to continue cooperation in this study, adequate spinal anesthesia and its conversion to general anesthesia, allergy to any of the drugs used, history of addiction, underlying pain such as back pain, headache, history of psychiatric drugs, receiving Preoperative housing, history of addiction

Intervention groups

Group A, which is the control group, receives 10 mg of bupivacaine, which has reached a volume of 10 ml with normal saline, which is injected by the surgeon at the incision site at the end of the operation. Group B, which is the intervention group, receives 100 mg of tramadol, which has reached a volume of 10 ml with normal saline, and is finally injected by the surgeon at the incision site. Group C, which is the intervention group, receives 10 mg of bupivacaine and 100 mg of tramadol, which has reached a volume of 10 ml with normal saline, is finally injected by the surgeon at the incision site.

Main outcome variables

The degree of pain, itching. nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110306005993N3**

Registration date: **2021-11-14, 1400/08/23**

Registration timing: **retrospective**

Last update: **2021-11-14, 1400/08/23**

Update count: **0**

Registration date

2021-11-14, 1400/08/23

Registrant information

Name

Seyed Abdollah Emadi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-19, 1400/05/28

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparision of intraincisional bupivacaine, tramadol and bupivacaine plus tramadol in postoperative pain in elective cesarean section patients

Public title
Comparision of intraincisional bupivacaine, tramadol and bupivacaine plus tramadol in postoperative pain in elective cesarean section patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 15-45 years Have informed written consent to cooperate with the study Patient classification in class ASA1,2
Exclusion criteria:
The patient refused to continue collaborating in this study Adequate spinal anesthesia and its conversion to general anesthesia Allergy to any of the drugs used History of addiction Existence of underlying pain such as back pain, headache History of using psychiatric drugs Get preoperative housing History of addiction

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be assigned to three groups through random blocking. A, B and C are 15 blocks of six randomly assigned blocking process and Random Allocation software is used. All 3 drugs are similar in appearance and volume and are responsible for preparing the mentioned drugs. Fill in syringes A, B and C and the anesthesia assistant injects the medicine into the patient according to the randomization block and random letters A, B and C without knowing the type of medicine. It is prepared in another room and delivered to the injector in the operating room.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drugs are prepared in a similar appearance and volume in another room and delivered to the injector in the operating room, where the patient injector and the

evaluator are kept blind according to the type of treatment groups of the patients.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Imam Hospital of Sari - Research Ethics Committee of Mazandaran University of Medical Sciences
Street address
Amir Mazandaran Blvd. Imam Khomeini Educational and Medical Center
City
Sari
Province
Mazandaran
Postal code
33131 - 48166
Approval date
2021-08-11, 1400/05/20
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1400.024

Health conditions studied

1

Description of health condition studied
Cesarean section pain control
ICD-10 code
O82.1
ICD-10 code description
Delivery by emergency caesarean section

Primary outcomes

1

Description
The amount of pain
Timepoint
Intervals 6, 12 and 24 hours after surgery
Method of measurement
The Visual Analogue Scale (VAS) consists of a pain ruler that includes a horizontal line that is graded from zero to 10, with a 0-1 sign of pain 2-3 mild pain 4-6 moderate pain and 7 or more It is a sign of severe pain. In addition, it has various visual forms to determine the severity of pain.

Secondary outcomes

1

Description

Nausea and vomiting

Timepoint

Intervals of 6, 12 and 24 hours

Method of measurement

Yes-no based on patient observations and statements

Intervention groups

1

Description

Intervention group: The recipient of 100 mg of tramadol, which has reached a volume of 10 ml with normal saline, is finally injected by the surgeon at the incision site.

Category

Prevention

2

Description

Intervention group: The recipient receives 10 mg of bupivacaine and 100 mg of tramadol, which has reached 10 ml of normal saline, at the end of the operation by the surgeon at the incision site.

Category

Prevention

3

Description

Control group: Receiver of 10 mg of bupivacaine, which has reached a volume of 10 ml with normal saline, which is injected by the surgeon at the incision site at the end of the operation.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Sari Anesthesiology Department

Full name of responsible person

Doctor SeyedAbdollah Emadi

Street address

Amir Mazandarani Blvd. Imam Khomeini Hospital Anesthesiology Department

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saedi

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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

Mazandaran 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

Doctor Seyed Abdollah Emadi

Position

Assistant Professor, Faculty, Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Doctor Seyed Abdollah Emadi

Position

Assistant Professor, Faculty, Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Hamid Qaderian

Position

Specialist Assistant in Anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

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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