# 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
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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**

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

**Public title**

Comparsion 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
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## Sponsors / Funding sources

### 1

**Sponsor**
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**Full name of responsible person**
Majid Saedi
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**Web page address**
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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**
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**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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## 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