# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Comparison of pain intensity and intrathecal complications of 50 and 100 µg morphine with very low dose of naloxone in patients undergoing cesarean section

## Protocol summary

**Study aim**
Comparison of pain intensity and intrathecal complications of 50 (group 50) and 100 (group 100) micrograms of morphine with very low dose of naloxone in patients undergoing cesarean section

**Design**
Clinical trial without control group with parallel parallel randomized bilateral groups of phase 2 on 94 patients with Sequentially numbered, sealed, opaque envelopes method

**Settings and conduct**
Location of Imam Khomeini Hospital, Sari, 13. Patients in group 1 will receive 50 micrograms of intrathecal morphine with bupivacaine and in group 2, 100 micrograms of intrathecal morphine with bupivacaine. And assessors and assistants who visit the patient and complete the questionnaire every 6 hours 24 hours after surgery are kept blind.

**Participants/Inclusion and exclusion criteria**
Introduction: Informed consent to participate in the study • Age over 18 years • Pregnant women with prior planning for cesarean section without major comorbid disease ) • First or second pregnancy • Willingness to give birth by cesarean section under spinal anesthesia Exclusion criteria: Dissatisfaction to participate in the study • Any contraindications to anesthesia with spinal technique • History of any allergy or idiocyncratic reaction to opioid drugs • Pain syndrome Chronic or regular use of opioids • Predictable evidence of fetal abnormality • Allergy or intolerance to ketorolac, ibuprofen or oxycodone • Body mass index above 40 • Failure of spinal anesthesia • Prolonged operation time

**Intervention groups**
Patients in group 1 will receive 50 micrograms of intrathecal morphine with bupivacaine and in group 2, 100 micrograms of intrathecal morphine with bupivacaine.

**Main outcome variables**
Reduce pain intensity

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20091219002883N6**
Registration date: **2021-10-21, 1400/07/29**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-21, 1400/07/29**
Update count: **0**

**Registration date**
2021-10-21, 1400/07/29

**Registrant information**

**Name**
Mohammadreza Habibi

**Name of organization / entity**
Mazandarn University of Medical Sciences and Health Services

**Country**
Iran (Islamic Republic of)

**Phone**
+98 15 1222 3023

**Email address**
mhabibi@mazums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-10-17, 1400/07/25

**Expected recruitment end date**
2021-12-16, 1400/09/25

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of pain intensity and intrathecal complications of 50 and 100 µg morphine with very low dose of naloxone in patients undergoing cesarean section

**Public title**

Comparison of pain intensity and intrathecal complications of 50 and 100 µg morphine with very low dose of naloxone in patients undergoing cesarean section

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age over 18 years Pregnant women with prior planning for cesarean section without Majo disease Absence of pregnancy-induced disease such as preeclampsia Term twin pregnancy (37 to 42 weeks) First or second pregnancy Tendency to cesarean delivery by spinal anesthesia

**Exclusion criteria:**

Dissatisfaction with participating in the study Any contraindications to anesthesia with spinal technique History of any idiocyncratic allergy or reaction to opioid drugs Chronic pain syndrome or regular use of opioids There is predictable evidence of anomaly in the fetus Allergy or intolerance to ketorolac, ibuprofen or oxycodone • Body mass index above 40 Failure of spinal anesthesia Prolongation of operation time

**Age**

From **18 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **94**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization In this method, a random sequence is first created using Snose software, Random Allocation version 2 software will be used for random arrangement of samples in blocks. In this software, we set the number of groups to 2, the number of samples to 47, the size of the blocks to be equal, and the coding to be a combination of letters, numbers, and random. Then, based on the sample size, read a number of envelopes with wrappers Aluminum (in order to obscure the contents of the envelopes), is prepared and each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. (Example: TF8G written on the envelope and the card inside the intervention envelope). Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, according to the order of entry of eligible participants to the study, one of the envelopes of the letter is opened and the assigned group of the participant is revealed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The SNOSE method is used to hide (blind) random allocation. This method is one of the common methods in concealing random allocation. The researcher, assistant and anesthesiologist who is given a sample to inject, evaluate and analyze the data are kept blind in the study.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Mazandaran University of Medical Sciences

**Street address**

Amir Mazandarani Blvd. Imam Khomeini Educational and Medical Center

**City**

Sari

**Province**

Mazandaran

**Postal code**

33131 - 48166

**Approval date**

2021-09-15, 1400/06/24

**Ethics committee reference number**

IR.MAZUMS.IMAMHOSPITAL.REC.1400.036

## Health conditions studied

### 1

**Description of health condition studied**

کنترل درد در جراحی سزارین

**ICD-10 code**

G89.29

**ICD-10 code description**
Other chronic pain

## Primary outcomes

### 1

**Description**
Reduce pain
**Timepoint**
The first 24 hours after cesarean section
**Method of measurement**
Visual Analogue Scale

## Secondary outcomes

### 1

**Description**
The rate of nausea
**Timepoint**
Once every 6 hours for the first 24 hours after surgery
**Method of measurement**
questionnaire

## Intervention groups

### 1

**Description**
50 micrograms of intrathecal morphine with bupivacaine will be injected intravenously with 20 ng of naloxone after entering the operating room. Number of injections 1 time
**Category**
Treatment - Drugs

### 2

**Description**
100 micrograms of intrathecal morphine with bupivacaine will be injected intravenously with 20 ng of naloxone after entering the operating room.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Imam Khomeini Medical Center
**Full name of responsible person**
Mohammad faraji rad
**Street address**
Amir Mazandarani Blvd., Imam Khomeini Educational and Medical Center
**City**
Sari
**Province**
Mazandaran
**Postal code**
33131 - 48166
**Phone**
+98 11 3336 1700
**Fax**
+98 11 3336 1700
**Email**
m.farajirad@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Mazandaran University of Medical Sciences
**Full name of responsible person**
Majid Saedi
**Street address**
Moallem Square, Vice Chancellor for Research, Mazandaran University of Medical Sciences
**City**
Sari
**Province**
Mazandaran
**Postal code**
48157-33971
**Phone**
+98 11 3325 7230
**Fax**
+98 11 3325 7230
**Email**
m.saedi@mazums.ac.ir
**Web page address**
https://www.mazums.ac.ir
**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**
Dr. Mohammadreza Habibi

**Position**
Associate Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Cardiology
**Street address**
Mazandaran Heart Center; fattemeh alzahra Hos. Sari
**City**
Sari
**Province**
Mazandaran
**Postal code**
48157-33971
**Phone**
+98 11 3332 3023
**Fax**
+98 11 3332 3023
**Email**
mohammadreza.habibi@gmail.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Mazandaran University of Medical Sciences
**Full name of responsible person**
Muhammad faraji rad
**Position**
Resident anesthesia
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Anesthesiology
**Street address**
Amir Mazandarani Blvd., Imam Khomeini Educational and Medical Center
**City**
Sari
**Province**
Mazandaran
**Postal code**
33131 - 48166
**Phone**
+98 11 3336 1700
**Fax**
+98 11 3336 1700
**Email**
m.farajirad@yahoo.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Mazandaran University of Medical Sciences
**Full name of responsible person**
Muhammad faraji rad
**Position**
Resident anesthesia
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Anesthesiology
**Street address**
Amir Mazandarani Blvd., Imam Khomeini Educational and Medical Center
**City**
Sari
**Province**
Mazandaran
**Postal code**
33131 - 48166
**Phone**
+98 11 3336 1700
**Fax**
+98 11 3336 1700
**Email**
m.farajirad@yahoo.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