

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 idiosyncratic 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

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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

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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

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Amir Mazandarani Blvd., Imam Khomeini Educational and Medical Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Dr. Mohammadreza Habibi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Latest degree

Medical doctor

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Anesthesiology

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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