

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of patient-controlled analgesia versus intrathecal opioid injection on patient satisfaction with pain control after cesarean section

Protocol summary

Study aim

The effect of patient-controlled analgesia versus intrathecal opioid injection on patient satisfaction with pain control after cesarean section

Design

Phase III randomized trial with parallel groups on 60 patients, randomization with a randomization table by the Random Allocation software

Settings and conduct

This study will be performed on 60 candidates for elective cesarean section referred to Khalij Fars and Shariati Hospitals, Bandar Abbas. Patients will be randomized into two groups based on a randomization table. In the 1st intervention group, 3 ml spinal anesthesia solution containing 12 mg bupivacaine 0.5% and 20 mg pethidine will be injected intrathecally. In the 2nd intervention group normal saline with the same amount of pethidine will be included in the solution. Also, a patient-controlled analgesia (PCA) pump containing morphine at 1 mg/h will be set up in the recovery for these patients. Patient satisfaction with pain control will be assessed after gaining consciousness in the recovery and then at 1, 4, and 24 hours in the ward, using a numerical rating scale (NRS). Also, pruritus, nausea and/or vomiting, and respiratory depression will be assessed up to 24 hours after surgery. Given the nature of the interventions blinding will not be possible.

Participants/inclusion and exclusion criteria

Inclusion criteria: pregnancy; elective cesarean section; ASA class I and II; age of 18-46 years. Exclusion criteria: emergency cesarean section; intraoperative complication of cesarean section.

Intervention groups

Intervention 1: 3 ml spinal anesthesia solution containing 12 mg bupivacaine 0.5% and 20 mg pethidine injected intrathecally. Intervention 2: 3 ml spinal anesthesia solution containing 12 mg bupivacaine 0.5% and normal saline injected intrathecally. Also, a PCA pump of morphine at 1 mg/h will be set up in the recovery.

Main outcome variables

Patient satisfaction with pain control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220411054492N1**

Registration date: **2022-07-25, 1401/05/03**

Registration timing: **retrospective**

Last update: **2022-07-25, 1401/05/03**

Update count: **0**

Registration date

2022-07-25, 1401/05/03

Registrant information

Name

Abbas Moallem

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3371 0370

Email address

moallemyaln@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-01, 1395/12/11

Expected recruitment end date

2018-02-01, 1396/11/12

Actual recruitment start date

2017-03-01, 1395/12/11

Actual recruitment end date

2018-02-01, 1396/11/12

Trial completion date

2018-02-01, 1396/11/12

Scientific title

Effect of patient-controlled analgesia versus intrathecal opioid injection on patient satisfaction with pain control after cesarean section

Public title

Patient-controlled analgesia versus intrathecal opioid for pain after cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnancy Elective cesarean section ASA class I and II
Age: 18-46 years old

Exclusion criteria:

Emergency cesarean section Complications during cesarean section

Age

From **18 years** old to **46 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized into two groups using simple randomization with individuals as the unit of randomization and a randomization table produced by the Random Allocation software. Allocation concealment will be done using unclear envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hormozgan University of Medical Sciences

Street address

Imam Hossein Blvd., across from Kargaran Sports

Complex, Faculty of Medicine

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2017-01-09, 1395/10/20

Ethics committee reference number

IR.HUMS.REC.1395.135

Health conditions studied**1****Description of health condition studied**

Post-cesarean section pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes**1****Description**

Patient satisfaction with analgesia

Timepoint

After gaining consciousness in the recovery and then at 1, 4, and 24 hours in the ward

Method of measurement

Numerical rating scale (NRS)

Secondary outcomes**1****Description**

Drug side effects

Timepoint

Up to 24 hours after surgery

Method of measurement

Pruritus, nausea and/or vomiting, and respiratory depression (respiratory rate <10/min)

Intervention groups**1****Description**

Intervention group 1: 3 ml spinal anesthesia solution containing 12 mg bupivacaine 0.5% (MYLAN S.A.S, France) and 20 mg pethidine (Exir Pharmaceutical Co., Iran) injected intrathecally.

Category

Prevention

2

Description

Intervention 2: 3 ml spinal anesthesia solution containing 12 mg bupivacaine 0.5% (MYLAN S.A.S, France) and normal saline injected intrathecally. Also, a PCA pump of morphine (Iran Tajhiz Co., Iran) at 1 mg/h will be set up in the recovery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital, Bandar Abbas

Full name of responsible person

Abbas Moallem

Street address

Dr. Ali Shariati Hospital, Shahid Naser Blvd., Next to the Revolutionary Court, Bandar Abbas, Hormozgan

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2

Recruitment center

Name of recruitment center

Khalij Fars Hospital, Bandar Abbas

Full name of responsible person

Abbas Moallem

Street address

Khalij Fars Hospital, Azad University Blvd., Bandar Abbas, Hormozgan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery for Research Hormozgan University of Medical Sciences

Full name of responsible person

Teamur Aghamolaei

Street address

Imam Hossein Blvd., across from Kargaran Sports Complex

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Email

teaghamolaei@gmail.com

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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

Vice-Chancellery for Research Hormozgan 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Abbas Moallem

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available