Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 intathecally. 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 intathecally. Intervention 2: 3 ml spinal anesthesia solution containing 12 mg bupivacaine 0.5% and normal saline injected intathecally. 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 Moallemy
Name of organization / entity
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Iran (Islamic Republic of)
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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 intathecally.

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 intathecally. 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 Moallemy

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
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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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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 Moallemy

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Latest degree

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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