Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Comparing the effect of adding intrathecal morphine or pethidine to bupivacaine in spinal anesthesia during cesarean section surgery on post-operative pain of pregnant women with a gestational age of over 37 weeks

Protocol summary

Study aim
The effect of adding intrathecal morphine or pethidine to bupivacaine spinal anesthesia will be compared in this research.

Design
This randomized two-armed parallel group (55 subjects) trial will be double-blinded. Randomization will be applied by random allocation software.

Settings and conduct
This study will be performed on pregnant women ready for cesarean section in Bandar Abbas, Iran, in Shariati and Persian Gulf hospitals in the years 2017-2018. Upon approval of the protocol by the Theses Committee of the School of Medicine and the Ethics Committee of the University the participating pregnant women, the second anesthesiologist and the medical student will be blinded. The desired variables will be recorded during the study. After a 10 cc/kg of ringer serum pre hydration, spinal anesthesia will be applied in a sitting position, with a Quincke needle (number.25), at lumbar spaces 3-4 or 4-5 with a total volume of 3 milliliters of anesthetic solution.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18-50, gestational age of over 37 weeks and the American Society of Anesthesiologists physical status classes I and II and candidate for a cesarean section surgery. Exclusion criteria: Emergency cesarean section, Limitations for applying regional block, Valvular heart disease, A history of allergy to the target drugs, Addicts, Alcoholics, Preeclampsia, Diabetes, Unwillingness to take part in the research.

Intervention groups
The group 1 will receive 12 mg of bupivacaine (0.5%) plus 200 µg of morphine and group 2 will receive 12 mg of bupivacaine (0.5%) plus 20 mg of pethidine.

Main outcome variables
Hemodynamic parameters, pain, respiratory rate, sedation, nausea and vomiting, and itching will be recorded.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140615018091N10**
Registration date: **2020-04-15, 1399/01/27**
Registration timing: **retrospective**

Last update: **2020-04-15, 1399/01/27**
Update count: **0**

Registration date
2020-04-15, 1399/01/27

Registrant information

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Fekrat Fereydoon

Name of organization / entity
Hormozgan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-06-05, 1396/03/15

Expected recruitment end date
2017-09-27, 1396/07/05

Actual recruitment start date
2017-07-11, 1396/04/20
Actual recruitment end date
2018-05-08, 1397/02/18
Trial completion date
2018-05-10, 1397/02/20

Scientific title
Comparing the effect of adding intrathecal morphine or pethidine to bupivacaine in spinal anesthesia during cesarean section surgery on post-operative pain of pregnant women with a gestational age of over 37 weeks

Public title
Comparing the effect of adding morphine or pethidine to bupivacaine into the spinal space while producing numbness for cesarean section surgery on post-operative pain of pregnant women with a pregnancy age of over 37 weeks
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-50 Gestational age of over 37 weeks American Society of Anesthesiologists physical status classes I and II Candidate for a cesarean section surgery
Exclusion criteria:
Emergency cesarean section Limitations for applying regional block, Valvular heart disease A history of allergy to the target drugs Addicts Alcoholics Preeclampsia Diabetes Unwillingness to take part in the research
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **110**
Actual sample size reached: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation software will be used to design a permuted block randomization table with a 1:1 allocation. Block sizes of 2, 4 and 6 will be used. According to the size of each block concealed opaque sequentially numbered envelopes containing the either assigned group A or B will be drawn. Allocation concealment and blinding to the block sizes will be applied to the primary anesthesiologist responsible for applying the study protocol.
Blinding (investigator's opinion)
Double blinded
Blinding description
The following group of people involved in the blinding is: The participating parturients involved in the study will not be aware of the type of drug being injected intrathecally. However, written informed consent will be obtained from the participants. A second anesthesiologist who is participating in the trial but is not in charge of patient care will be responsible for collecting data in the operating room and will be blinded to the designation group of the pregnant participants and medications prescribed in the protocol. The medical student responsible for collecting the results of the study will also be blinded to the inclusion of parturients in the groups and the drugs prescribed in the protocol.
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
Anesthesiology Research Center, Shahid Mohammadi Hospital, Islamic Republic Blvd.
City
Bandar Abbas
Province
Hormozgan
Postal code
7919915519
Approval date
2017-11-26, 1396/09/05
Ethics committee reference number
HUMS.REC.1396.108

Health conditions studied

1

Description of health condition studied
pregnancy
ICD-10 code
ICD-10 code description

2

Description of health condition studied
spinal anesthesia
ICD-10 code
ICD-10 code description

3

Description of health condition studied

hemodynamic changes
ICD-10 code
ICD-10 code description

4

Description of health condition studied
postoperative pain
ICD-10 code
G89.18
ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
severity of post surgical pain
Timepoint
1st, 4th and 24th hours after surgery
Method of measurement
Numeric Rating Scale

2

Description
the first demand for analgesia
Timepoint
after the surgery
Method of measurement
minutes after the surgery

3

Description
dose of the analgesic
Timepoint
after the surgery
Method of measurement
the number of diclofenac suppositories (100 mg) applied

Secondary outcomes

1

Description
Nausea and vomiting
Timepoint
1st, 4th and 24th hours after surgery
Method of measurement
Quantitative frequency will be recorded on questionnaire

2

Description
Itching
Timepoint
During surgery and in the 1st, 4th and 24th after the surgery
Method of measurement
Quantitative frequency will be recorded on questionnaire

3

Description
Blood pressure (systolic and diastolic)
Timepoint
The first 10 minutes will be measured every 3 minutes and then every 5 minutes till the end of the surgery. Post-operatively at the 1st, 4th and 24th hours.
Method of measurement
Non-invasive blood pressure device

4

Description
Respiratory rate
Timepoint
Within the first 10 minutes every 3 minutes and then every 5 minutes till the end of the surgery. Post-operatively at the 1st, 4th and 24th hours.
Method of measurement
Respiration monitoring by using Electrocardiograph device

5

Description
Sedation condition
Timepoint
During the surgery as well as in the 1st, 4th and 24th hours after surgery.
Method of measurement
Ramsey Sedation Scale

6

Description
Assessment for infants health condition after delivery
Timepoint
1st and 5th minutes of birth
Method of measurement
Apgar score

7

Description
Shivering
Timepoint
During the surgery and in the 1st, hours after surgery.
Method of measurement
Quantitative frequency recorded on questionnaire

Intervention groups

1

Description
The first intervention group parturients while being in the sitting position, a Quincke needle No. 25 will be inserted into the lumbar space 3-4 or 4-5 and a total volume of 3 ml of a solution containing 12 mg of bupivacaine (0.5 %))BUPIVACAINE MYLAN 20MG/4ML, Haupt Pharma Livron S.A.S. CO.) with 200 micrograms of morphine sulfate (Alborz Daru CO.) will be injected into the subarachnoid

spaces.

Category

Treatment - Drugs

2

Description

The second intervention group parturients while being in the sitting position, a Quincke needle No. 25 will be inserted into the lumbar space 3-4 or 4-5 and a total volume of 3 ml of a solution containing 12 mg of bupivacaine (0.5 %))BUPIVACAINE MYLAN 20MG/4ML, Haupt Pharma Livron S.A.S CO.) with 20 mg of pethidine (Caspian Tamin CO.) will be injected into the subarachnoid spaces.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati Hospital
Full name of responsible person
Abbas Moallemy
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2

Recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Bandare-abbas 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
Fereydoon Fekrat
Position
specialist in Anesthesiology and Intensive care
Latest degree
Specialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All collected deidentified IPD will be available.
When the data will become available and for how long
Starting 12 months after publication.
To whom data/document is available
This will be only made available for people working in academic institutions.
Under which criteria data/document could be used
The requests for review will be answered according to the policies provided by the body of regulations that is stated by the Vice-chancellor of research of Hormozgan University of medical sciences.
From where data/document is obtainable
Requests can be sent to Dr. Abbas Moellemy at moallemyaln@yahoo.com
What processes are involved for a request to access data/document
The request for deidentified participant data review will be evaluated by the anesthesiology research center vice-chancellor and referred to the Hormozgan university vice-chancellor for assessing the eligibility of the requesting party this may take 1-3 months.
Comments