

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of intrathecal administration of bupivacaine and fentanyl with bupivacaine and dexmedetomidine on postoperative analgesia in cesarean section

Protocol summary

Study aim

Reduce pain and better recovery after cesarean section

Design

A clinical trial of 55 patients with two treatments parallel groups of 55 patients(Fentanyl and Dexmedetomidine,added to intrathecal Bupivacaine), double-blind, Randomised with Random allocation software

Settings and conduct

This study will be done at Hormozgan University of Medical Sciences. Spinal anesthesia were done in the sitting position through the aseptic technique using 25 G Quincke spinal needle at the L4-5 interspace. After observing free flow of CSF, the patients will randomly allocated into two groups (n= 55) as follows: I.Group B-D received 10 mg hyperbaric Bupivacaine 0.5% + 5µg Dexmedetomidine [total volume of 2.5cc] II.Group B-F received 10 mg hyperbaric Bupivacaine 0.5% + 25 µg Fentanyl [total volume of 2.5cc] Hemodynamic parameters will be recorded in 0 minutes (immediately after injection), 5-10-15-30-60 minutes and in recovery.

Participants/Inclusion and exclusion criteria

110 pregnant women Inclusion criteria: Gestational age ≥ 37 weeks and candidate for cesarean section by spinal anesthesia, and physical classes 1,2(ASA I, II) Exclusion criteria: Emergency patients, patients with regional block bans, patients with heart valve disease, patients with a history of drug allergy, addictive or alcoholic patients, patients with placenta previa

Intervention groups

The first group received 10mg bupivacaine + 5µg dexmedetomidine The second group received 10mg bupivacaine + 25µg fentanyl

Main outcome variables

Systolic blood pressure Diastolic blood pressure Mean arterial pressure Arterial Oxygen Saturation Percentage nausea and vomiting Shivering Apgar score

Postoperative pain Duration of analgesia

General information

Reason for update

Problem writing

Acronym

IRCT registration information

IRCT registration number: **IRCT20110313006044N2**

Registration date: **2020-02-15, 1398/11/26**

Registration timing: **prospective**

Last update: **2020-03-31, 1399/01/12**

Update count: **1**

Registration date

2020-02-15, 1398/11/26

Registrant information

Name

Hashem Jarineshin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3334 5009

Email address

hjarineshin@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of intrathecal administration of bupivacaine and fentanyl with bupivacaine and dexmedetomidine on postoperative analgesia in cesarean section

Public title
To investigate the effect of dexmedetomidine and fentanyl on spinal analgesia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for elective cesarean section and gestational age ≥ 37 weeks
Exclusion criteria:
Emergency patients Patients with a ban on regional block Patients with heart valve disease Patients with a history of allergy to the drugs used Addictive or alcoholic patients Patients with placenta parvia Patients who require medication during surgery because of incomplete blockage

Age
From **16 years** old to **41 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was performed based on Random allocation software and based on that even numbers were considered for dexmedetomidine and odd numbers were considered for fentanyl accordingly. The numbers were put in closed envelopes and opened by a person other than the procedure handler, and according to which the drugs were prepared for injection they were given to the procedure physician while the doctor did not know the details of the syringes.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to eliminate bias from patient's awareness or anesthesia assistant and person who evaluate the results and its possible impact on the outcome of the study, the study will be conducted in a double-blind condition. After receiving written informed consent from patients, spinal anesthesia was done by given the same drugs and same volume to the anesthesiologist, then relevant information was recorded in the questionnaire by the anesthesiologist who was not aware of the injection of

the drugs. It is obvious that the patient and the anesthesiologist were not aware of the type of drug being administered.

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
Jomhuri Blvd, Shahid Mohammadi Hospital
City
Bandar Abbas
Province
Hormozgan
Postal code
9791991551

Approval date
2016-03-14, 1394/12/24

Ethics committee reference number
IR.HUMS.REC.1394.185

Health conditions studied

1

Description of health condition studied
Cesarean section

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain rate and duration of analgesia

Timepoint
Measurement of pain and duration of analgesia in recovery and during 6-3 hours after surgery

Method of measurement
Patients' severity of pain is based on the Visual Analogues Scale, with the left side indicating no pain and the right side showing the number "10" indicating the most severe pain. Score style 1-3 indicates mild pain, 4-7 moderate pain, severe pain 8-10), duration of analgesia from time to block until patient requests for analgesics

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

Intervention group 1: 10mg bupivacaine 0.5% + 5mg dexmedetomidine(PrecedexTM 200mcg/2ml Hospira, Inc,lake Forest, IL60045USA)

Category

Treatment - Drugs

2

Description

Intervention group 2: 10mg bupivacaine 0.5% + 25mg fentanyl(ROTEXMEDICA 0.5 mg/10ml 22946TRITTAU. Germany)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital Of Hormozgan University of Medical Sciences

Full name of responsible person

Hashem Jarineshin

Street address

Jomhuri Blvd, Shahid Mohammadi Hospital

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Email

Hjarineshin@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Hashem Jarineshin

Street address

Jomhuri Blvd, Shahid Mohammadi Hospital

City

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Postal code

9791991551

Phone

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Email

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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

Hashem Jarineshin

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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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 data can be shared

When the data will become available and for how long

Starting the post-access period of the paper was accepted

To whom data/document is available

All researchers

Under which criteria data/document could be used

All researchers

From where data/document is obtainable

Correspondence Dr Hashim Jarineshin contact by email
hjarineshin@yahoo.com

What processes are involved for a request to access data/document

Details are available within a week at most

Comments**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

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