Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of intrathecal administration of bupivacaine and fentanyl with bupivacaine and dexmedetomedine 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 dexmedetomedine 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 Commitee 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 dexmedetomedine(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
City
Bandar Abbas
Province
Hormozgan
Postal code
9791991551
Phone
+98 76 3334 5009
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
Bandar Abbas
Province
Hormozgan
Postal code
9791991551
Phone
+98 76 3334 5009
Email
Hjarineshin@yahoo.com
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
Street address
Jomhuri Blvd, Shahid Mohammadi Hospital
City
Bandar Abbas
Province
Hormozgan
Postal code
9791991551
Phone
+98 76 3334 5009
Email
Hjarineshin@yahoo.com

Person responsible for scientific 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
Street address
Jomhuri Blvd, Shahid Mohammadi Hospital
City
Bandar Abbas
Province
Hormozgan
Postal code
9791991551
Phone
+98 76 3334 5009
Email
Hjarineshin@yahoo.com

Person responsible for updating data

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
Street address
Jomhuri Blvd, Shahid Mohammadi Hospital
City
Bandar Abbas
Province
Hormozgan
Postal code
9791991551
Phone
+98 76 3334 5009
Email
Hjarineshin@yahoo.com

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