

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of intrathecal Bupivacaine and Fentanyl with Bupivacaine and Dexmedetomidine on post operative pain of cesarean section in Shariati Hospital of Bandar Abbas in 2014

Protocol summary

Summary

Background and Objective: Pain is one of the most common post-operative complications. In the case of cesarean section the post-operative pain can result in some complications for both Mother and neonate. Many methods have been proposed for the post-operative pain. Intrathecal opioid or dexmedetomidine injections are two examples of these methods. The aim of this study is to compare the efficacy of intrathecal fentanyl and dexmedetomidine for post-operative analgesia in cesarean sections that took place in Shariati Hospital of Bandar Abbass during 2014. Method: Randomized with 2 blocks design is considered. Double blinding design will be provided by concealing the awareness of the patients and the researcher who is in charge of data collection from the type of intervention. A total of 110 pregnant women who are scheduled for elective cesarean section divided into two groups randomly. Inclusion criteria: Women between 15 and 45 years old; Gestational age 37 week or higher; ASA 1-2. Exclusion criteria: Emergency patients; patients with contraindication for regional anesthesia; patients with Valvular Heart Disease; patients with history of Allergy to local anesthetic drugs; addiction or alcoholism; Placenta Previa; patients with incomplete spinal block who require analgesic agents. Intervention: Group A received 10 mg bupivacaine 0.5% plus dexmedetomidine 5 microgram; group B received 10 mg bupivacaine 0.5% plus fentanyl 25 microgram intrathecally. Main measurable variables: pain score, and motor block time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052722449N1**
Registration date: **2015-11-02, 1394/08/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-02, 1394/08/11

Registrant information

Name

Mehdi Sharifi

Name of organization / entity

Hormozgan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 76 3334 5009

Email address

dr.msh53@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Hormozgan University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of intrathecal Bupivacaine and Fentanyl with Bupivacaine and Dexmedetomidine on

post operative pain of cesarean section in Shariati Hospital of Bandar Abbas in 2014

Public title
Comparison of the effect of Fentanyl with Dexmedetomidine on post operative pain of cesarean section

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Gestational age 37 weeks or higher; ASA I-II Exclusion criteria: Emergency patients; patients with valvular Heart disease; patients with history of Allergy to local anesthetic drugs; addiction and alcoholism; placenta previa; patients with incomplete spinal block who require analgesic agents; patients with contraindication for regional anesthesia

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomized with two-block design is considered. Double blinding design will be provided by concealing the awareness of the patients and the researcher who is in charge of data collection from the type of intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hormozgan University of Medical Sciences

Street address

Shahid Mohammadi Hospital, Joomhoori Islami Blvd., Bandar Abbas, Iran

City

Bandar Abbas

Postal code

7919915519

Approval date

2014-09-30, 1393/07/08

Ethics committee reference number

3-HEC-93-7-8

Health conditions studied

1

Description of health condition studied

Complication of Anesthesia during pregnancy

ICD-10 code

029.8

ICD-10 code description

other Complication of Anesthesia during pregnancy

Primary outcomes

1

Description

Post operative pain

Timepoint

Recovery time and 1 - 3 - 6 hours after operation

Method of measurement

VAS (visual analogue scale)

2

Description

The duration of complete return of lower extremities movement (Modified Bromage Scale = 0)

Timepoint

Recovery time and 1 - 3 - 6 hours after operation

Method of measurement

Lower extremities movement (modified Bromage scale)

Secondary outcomes

1

Description

respiratory depression

Timepoint

For 6 hours after block initiation

Method of measurement

respiratory rate less than 10 per minute

2

Description

nausea and vomiting

Timepoint

For 6 hours after block initiation

Method of measurement

Questionnaire (Yes or NO)

3

Description

shivering

Timepoint

For 6 hours after block initiation

Method of measurement

Questionnaire (Yes or NO)

4

Description

blood pressure

Timepoint

Before injection and immediately after injection and at 5-10-15-30-60 minutes after injection and at recovery

Method of measurement

Automated sphygmomanometer

5

Description

heart rate

Timepoint

Before injection and immediately after injection and at 5-10-15-30-60 minutes after injection and at recovery

Method of measurement

heart rate monitoring device

Intervention groups

1

Description

Group 2: Intrathecal 10 mg bupivacaine 0.5% plus 25 microgram fentanyl

Category

Treatment - Drugs

2

Description

Group 1: Intrathecal 10 mg bupivacaine 0.5% plus 5 microgram dexmedetomidin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Mehdi Sharifi

Street address

Shariati Hospital, Shahid Naser Blvd., Bandar Abbas, Iran

City

Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Hormozgan University of Medical Sciences

Full name of responsible person

Abdolazim Nejatizadeh

Street address

Vice chancellor for Research, Shahid Mohammadi Hospital, Joomhoori Islami Blvd., Bandar Abbas, Iran

City

Bandar Abbas

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Hormozgan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Mehdi Sharifi

Position

Resident of Anesthesiology

Other areas of specialty/work

Street address

Shahid Mohammadi Hospital, Joomhoori Islami Blvd., Bandar Abbas, Iran

City

Bandar Abbas

Postal code

00987633347009

Phone

+98 76 3334 7009

Fax

Email

dr.msh53@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Mehdi Sharifi

Position
Resident of Anesthesiology
Other areas of specialty/work
Street address
Shahid Mohammadi Hospital, Joomhoori Islami Blvd.,
Bandar Abbas, Iran
City
Bandar Abbas
Postal code
Phone
+98 76 3334 7009
Fax
Email
dr.msh53@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Hormozgan University of Medical Sciences
Full name of responsible person
Mehdi Sharifi
Position
Resident of Anesthesiology
Other areas of specialty/work
Street address

Shahid Mohammadi Hospital, Joomhoori Islami Blvd., ,
Bandar Abbas, Iran
City
Bandar Abbas
Postal code
Phone
+98 76 3334 7009
Fax
Email
dr.msh53@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty