

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the effect of Fentanyl and Sufentanil added to intrathecal Bupivacaine on post operative pain after elective cesarean section in pregnant women

Protocol summary

Summary

The current study was a prospective double blind randomized clinical trial, phase 2, one center. The study population was comprised of pregnant women who were candidates for elective cesarean section and had signed written consent. Sampling in this study was based on inclusion and exclusion criteria. The Randomization was done using random number table. The person who assessed the patients and patient who accepted to be put under treatment were blind to the group allocation. Patients in one group received 10 mg bupivacaine 0.5% plus 25 mg fentanyl while Patients in other group received 10 mg of 0.5% bupivacaine plus 5 µg of sufentanil through injection in to the cerebrospinal fluid using a 5 cc syringe, at the intrathecal space in a completely sterile condition. Inclusion criteria included all pregnant women classified as class I or II of ASA (American Society of Anesthesiologists) who were candidate for elective cesarean section. Exclusion criteria: pregnant women who were not satisfied with spinal anesthesia. Primary outcome measures were included anesthesia level, blood pressure, analgesia level and secondary outcome measures were nausea and vomiting

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101530303N1**

Registration date: **2017-03-21, 1396/01/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-21, 1396/01/01

Registrant information

Name

Abbas Paknahad

Name of organization / entity

Hormozgan University of Medical Sciences.

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hormozgan University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Fentanyl and Sufentanil added to intrathecal Bupivacaine on post operative pain after elective cesarean section in pregnant women

Public title

Comparison of the effect of Fentanyl and Sufentanil added to Bupivacaine on post-cesarean pain.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: class I or II of ASA (American Society of Anesthesiologists; candidate for elective cesarean section; no history of heart disease, hypertension, preeclampsia, gestational diabetes; being satisfied to receive intrathecal anesthesia and participate in the study. Exclusion criteria: contraindication for spinal anesthesia; presence of infection in the needle insertion site; high intracranial pressure; coagulopathy; platelet count lower than 75000.

Age
From **10 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization has been done using random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences, Bandar Abbas.

Street address

Shahid Mohammadi Hospital, Bandar Abbas.

City

Bandar Abbas

Postal code

7468178978

Approval date

2015-06-06, 1394/03/16

Ethics committee reference number

HUMS.REC.1394.163

Health conditions studied

1

Description of health condition studied

Pain after cesarean section

ICD-10 code

080-084

ICD-10 code description

Delivery

Primary outcomes

1

Description

The numbness

Timepoint

3 times (every 8 hours) in the first 24 hours.

Method of measurement

Questionnaire

2

Description

Blood Pressure

Timepoint

Monitoring during the first 24 hours.

Method of measurement

Questionnaire

3

Description

Analgesia

Timepoint

3 times (every 8 hours) in the first 24 hours.

Method of measurement

Questionnaire

Secondary outcomes

1

Description

nausea and vomiting

Timepoint

3 times (every 8 hours) in the first 24 hours.

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group 1: 10 mg of 0.5% bupivacaine with 25 micrograms of fentanyl prescribed intrathecally into cerebrospinal fluid, at the space between the vertebrae 4 and 5 lumbar in the midline, using a syringe 5 cc in sterile condition under the supervision of an anesthesiologist.

Category

Other

2

Description

Intervention group 2: 10 mg of 0.5% bupivacaine with 25 micrograms of sufentanil prescribed intrathecally into cerebrospinal fluid, at the space between the vertebrae 4 and 5 lumbar in the midline, using a syringe 5 cc in sterile condition under the supervision of an anesthesiologist.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Abbas Pak Nahad

Street address

Shariati hospital, Farhangian street, Bandar Abbas

City

Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Hormozgan University of Medical Sciences, Bandar Abbas.

Full name of responsible person

Abbas Pak Nahad, Dr. Manoochehr Kamali

Street address

Hormozgan University of Medical Sciences, Dabbaghian street, Bandar Abbas

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 of Hormozgan University of Medical Sciences, Bandar Abbas.

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

Anaesthesiology, Critical Care and Pain Management Research Center, Hormozgan University of Medical

Full name of responsible person

Abbas Pak Nahad

Position

BSc

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

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Student Research Committee, Hormozgan University of Medical Sciences, Bandar Abbas.

Full name of responsible person

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Position

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Other areas of specialty/work

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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