Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effects of intrathecal Fentanyl and Bupivacaine with Sufentanyl plus Bupivacaine on duration of post-operative pain and side effect in elective caesarean section in alzahra hospital

Protocol summary

Summary

The aim of this study is comparison of effects of intrathecal Fentanyl and Bupivacaine with Sufentanyl plus Bupivacaine on duration of post-operative pain and side effect in elective caesarean section. Inclusion criteria: ASA class 1 & 2: Age between 15-45 years old: Height between 150-170 centimeters Exclusion criteria: Time of operation lasts more than 1.5 hours; Intraoperative bleeding more than 1500 cc; the patient's inability to keep immobility during blocks. 90 patients randomly divided in 3 groups. All patients undergoing intrathecal anesthesia with Bupivacaine. Additionally group F receive Fentanyl, group S receive Sufentanyl and group P injected placebo. During surgery patients will monitor by pulse oximetry, non-invasive barometer and ECG. Blood pressure, heart rate, nausea, vomiting, itching, drowsiness, respiratory depression and Apgar score, sensory block level, motor block level; recovery of sensory block to T10, reversible motor block, pain and shivering and patient satisfaction assessment is evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506068677N6**
Registration date: **2015-06-29, 1394/04/08**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-06-29, 1394/04/08

Registrant information

Name

Farnoush Farzi

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of intrathecal Fentanyl and Bupivacaine with Sufentanyl plus Bupivacaine on duration of post-operative pain and side effect in elective caesarean section in alzahra hospital

Public title

The effects of intrathecal Fentanyl and Bupivacaine with Sufentanyl plus Bupivacaine on duration of post-operative pain and side effect in elective caesarean section in alzahra hospital

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ASA class 1 & 2: Age between 15-45 years old: Height between 150-170 centimeters
Exclusion criteria: The time of operation lasts more than 1.5 hours; Intraoperative bleeding more than 1500 cc; the patient's inability to keep immobility during blocks

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

Gender
Female

Phase
N/A

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
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Guilan University of Medical Sciences

Street address
Namjoo Avenue

City
Rasht

Postal code
4193893345

Approval date
2015-05-12, 1394/02/22

Ethics committee reference number
IR.GUMS.REC.1394.23

Health conditions studied

1

Description of health condition studied
Cesarean section

ICD-10 code
O82.9

ICD-10 code description
Delivery by caesarean section, unspecified

Primary outcomes

1

Description
Painless duration after surgery

Timepoint
The first 15 minutes every 3 minutes, 45 minutes later every 15 minutes, to 4 hours every 30 minutes, 3 hours later every 1 hour and 16 hours later every 4 hours

Method of measurement
According VAS score

2

Description
Using a pressure gauge

Timepoint
Since intrathecal anesthesia to birth every 3 minutes and then every 5 minutes

Method of measurement
Using pressure pomp

3

Description
Neonate APGAR

Timepoint
Minute 1 and 5 According

Method of measurement
APGAR criteria

4

Description
Complications

Timepoint
The first 15 minutes every 3 minutes, 45 minutes later every 15 minutes, to 4 hours every 30 minutes, 3 hours later every 1 hour and 16 hours later every 4 hours

Method of measurement
According patient's history

5

Description
Sensory block level and recovery of sensory block to T10

Timepoint
30 and 60 seconds after injection

Method of measurement
Using Pin prick method

6

Description
Motor block level and recovery of motor block

Timepoint
30 and 60 seconds after injection

Method of measurement
Using Bromage scale

Secondary outcomes

empty

Intervention groups

1

Description
Injection 12.5 milligrams Bupivacaine and 25 microgram Fentanyl
Category
Treatment - Drugs

2

Description
Injection 12.5 milligrams Bupivacaine and 2.5 milligram Sufentanyl
Category
Treatment - Drugs

3

Description
Injection 12.5 milligrams Bupivacaine and 0.5 milliliters normal saline
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Dr. Farnoosh Farzi
Street address
Namjoo Avenue
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Guilan University of Medical Sciences
Full name of responsible person
Abtin Heidarzadeh
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Shahid Beheshti Freeway
City
Rasht
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 Guilan 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
Guilan University of Medical Sciences
Full name of responsible person
Farnoosh Farzi
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Anesthesiologist
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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