Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A Comparative effect of fentanyl and meperidine added to 8 mg bupivacaine for spinal anesthesia in elective cesarean section surgery

Protocol summary

Summary

Objectives: Comparison the effect of intrathecal meperidine and fentanil added to bupivacaine 0.5% for elective Cesarean section. Study Design: a randomized, double-blind, clinical trial. Inclusion criteria: pregnant women, ASA I-II with singleton pregnancies who were underwent elective Caesarean section, Exclusion criteria: Patients with cardiovascular disorders, renal failure, coagulopathy, sensitivity to the drugs, preeclampsia, lack of consent and spinal anesthesia contraindication, history of seizures or other neurological diseases, (IUGR). 120 Patients were randomly divided into 3 groups: Group1 : bupivacaine 0.5% (8mg), 15 micrograms fentanil and 0.1 ml normal saline total volume 2ml.Group2 : bupivacaine 0.5% (8mg), 15 mg of meperidine and 0.1 ml normal saline total volume 2ml. Group3: bupivacaine 0.5% (10 mg) (total volume 2 ml. Measured variables: Time of onset: the time interval intrathecal injection and loss of sensation in the T10, The maximum level of sensory block and time to reach to the maximum level of sensory block, the level of sensory block after 120 min, the duration of sensory block, Onset of motor block, duration of motor block, the maximum level of motor block, shivering, pruritus, nausea, vomiting were checked during and after operation every 10 min in the recovery room every 10 min, Hypertension, bradycardia, time of discharge from recovery room, Apgar score at 1 and 5 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015013119470N14**
Registration date: **2015-02-09, 1393/11/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-09, 1393/11/20

Registrant information

Name
Farzaneh Masihi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Science

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative effect of fentanyl and meperidine added to 8 mg bupivacaine for spinal anesthesia in elective cesarean section surgery

Public title

A Comparative effect of fentanyl and meperidine added to 8 mg bupivacaine for spinal anesthesia in elective cesarean section surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women, ASA I-II with singleton pregnancies who were underwent elective Caesarean section, Exclusion criteria: Patients with cardiovascular disorders, renal failure, coagulopathy, sensitivity to the drugs, preeclampsia, lack of consent and spinal anesthesia contraindication, history of seizures or other neurological diseases, (IUGR).

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Shiraz University Of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

CP-P-9365-6925

Health conditions studied

1

Description of health condition studied

cesarean

ICD-10 code

O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

Determine the duration of sensory block in patients with intrathecal fentanyl added to bupivacaine 0.5%.

Timepoint

Perioperative and Post-operative

Method of measurement

Pinprick

Secondary outcomes

1

Description

To determine the duration of sensory block in patients receiving intrathecal meperidine with bupivacaine 0.5%.

Timepoint

Prioperative and post operative

Method of measurement

Pinprick Scale

Intervention groups

1

Description

Group1 : bupivacaine 0.5% (8mg), 15 micrograms fentanyl and 0.1 ml normal saline total volume 2ml.

Category

Treatment - Drugs

2

Description

Group2 :intrathecal bupivacaine 0.5% (8mg), 15 mg of meperidine and 0.1 ml normal saline total volume 2ml.

Category

Treatment - Drugs

3

Description

Group3:intrathecal bupivacaine 0.5% (10 mg) (total volume 2 ml)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research; Shiraz University of Medical Sciences
Full name of responsible person
Dr Seed Basir Hashemi
Street address
Vice Chancellor for Research, Shiraz University of Medical Sciences, 7th floor, Central Building of Shiraz University of Medical Sciences, Zand Street
City
Shiraz
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; Shiraz 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

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Person responsible for updating data

Contact

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