Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the Effects of Intrathecal Dexmedetomidine and Meperidine as Adjuvants to Bupivacaine 0.5% in the Woman Undergoing Elective Cesarean Section

Protocol summary

Summary

Objectives: The aim of this study was to compare the onset and duration of sensory and motor block, pruritus, shivering, and duration of analgesia and the effects in the newborn (Apgar) of dexmedetomidine or meperidine given intrathecally with 0.5% bupivacaine. Design: Conduction of a randomized, double-blind, clinical trial, method of randomization: simple randomization. Inclusion criteria: pregnant women, ASA I-II with singleton pregnancies who were underwent elective Caesarean section, term neonate, no contraindication for spinal anesthesia. Exclusion criteria: Patients with cardiovascular disorders, renal failure, coagulopathy, sensitivity to drugs, lack of consent and spinal anesthesia contraindication, history of seizures or other neurological diseases, (IUGR) Lack of proper growth of the fetus inside the uterus. 90 Patients were randomly divided into 3 groups to receive one of the following drugs for spinal anesthesia: Group D: 0.5% bupivacaine (10 mg) and dexmedetomidine 5 micrograms (Origin orion pharma Germany) (total volume 2.5 ml). Group M: 0.5% bupivacaine (10 mg) and 10 mg of meperidine (total volume 2.5 ml). Group P: 0.5% bupivacaine (10 mg) and 0.5 mL of normal saline without preservative (total volume 2.5 ml).Measured variables: Time of onset: the time interval intrathecal injection and loss of sensation in the T10 (by pinprick.),The time to reach the level of anesthesia to T6, The maximum level of sensory block (every 5 minutes or 20 minutes),The duration of sensory block (reduction of the maximum height of 2 level of sensory block), Onset of motor block Bromage score Modified about 1, The duration of motor block (reduced to zero and Modified Bromage score, The patient sedation (10 minutes after arrival to the recovery) based on the Modified ramsay sedation scale, Duration of anesthesia (spinal onset until the patient is complaining of pain), Apgar score at 1 and 5 minutes, Hypertension, Heart Rate, Nausea, vomiting, itching, shivering in recovery .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100814372N4**
Registration date: **2015-02-02, 1393/11/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-02, 1393/11/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Science

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2014-08-22, 1393/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effects of Intrathecal Dexmedetomidine and Meperidine as Adjuvants to Bupivacaine 0.5% in the Woman Undergoing Elective Cesarean Section

Public title

Comparison the Effects of Intrathecal Meperidine and Dexmedetomidine added to Bupivacaine in the Woman Undergoing Cesarean Section.

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women ASA I-II; singleton pregnancies; elective Caesarean section; term neonate; no contraindication for spinal anesthesia. Exclusion criteria :heart diseases; liver diseases; renal failure; coagulopathy; sensitivity to drugs; lack of consent; spinal anesthesia contraindication;a history of seizures; 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: **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

Ethic Committee of Shiraz University Of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Street

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Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

cp-c-9368-6738

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

the duration of sensory block

Timepoint

Perioperative every 20 min and Post-operative 10 min after arrival to the recovery room

Method of measurement

Pinprick

Secondary outcomes

empty

Intervention groups

1

Description

Patients in placebo group received 0.5% bupivacaine (10 mg) and 0.5 mL of normal saline without preservative (total volume 2.5 ml) for spinal anesthesia.

Category

Placebo

2

Description

Patients in intervention group 1 received 0.5% bupivacaine (10 mg) and dexmedetomidine 5 micrograms (Origin orion pharma Germany) (total volume 2.5 ml) for spinal anesthesia.

Category

Treatment - Drugs

3

Description

Patients in intervention group 2 received 0.5% bupivacaine (10 mg) and 10 mg of meperidine (total volume 2.5 ml) for spinal anesthesia.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafez Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Science
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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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