Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of analgesic effect of intrathecal sufentanil-bupivacaine versus dexmedetomedine -bupivacaine in cesarean delivery

Protocol summary

Summary

Background & Objective: pain is one of the most common post-op complication. In the case of cesarean the post-op pain can result in some complication for both mother and neonate. Many methods have been proposed for the post-op pain. Intratechal opioid or dexmedetomedine injections are two examples of these methods. In this study the efficacy of intratechal dexmedetomedine and sufentanil for post-op pain has been compared with each other. Design: Double blind clinical trial. Setting: patients were divided into two groups randomly: bupivacaine - dexmedetomedine and bupivacaine -sufentanil All patients was given Serum ringer 500cc and metocloperamide 10mg before spinal anesthesia Inclusion criteria: sixty ASA I, II full term pregnant women between 18 and 35 years who require for elective Cesarean Section. Exclusion criteria: patients with HTN, DM and other systemic disease. Intervention: Patients were randomly allocated to receive intrathecally either 10 mg hyperbaric bupivacaine plus 0.05 ml (5 µg) dexmedetomidine (group MD) or 10 mg hyperbaric bupivacaine plus 0.5 ml (2.5 µg) sufentanil (group MS). Main outcomes: BP, HR, nausea and vomiting, pain score

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307236625N2**
Registration date: **2013-09-08, 1392/06/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-09-08, 1392/06/17

Registrant information

Name

Mozaffar Rabiee

Name of organization / entity

Babaol university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor Of Research Babol University Of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-08-13, 1392/05/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of analgesic effect of intrathecal sufentanil-bupivacaine versus dexmedetomedine -bupivacaine in cesarean delivery

Public title

Duration of analgesia effect of intrathecal sufentanil-bupivacaine versus dexmedetomedine -bupivacaine in cesarean delivery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: sixty ASA I, II; full term pregnant; women between 18 and 35 years who require for

elective Cesarean Section. Exclusion criteria: patients with HTN; DM and other systemic disease

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

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
Ethics committee of Babol University Of Medical Sciences

Street address
Daneshgah Square, Ganjafrooz Avenue

City
Babol

Postal code

Approval date
2013-02-05, 1391/11/17

Ethics committee reference number
2006/30/ژ/پ

Health conditions studied

1

Description of health condition studied
complications of Anesthesia during pregnancy

ICD-10 code
029.8

ICD-10 code description
Other complications of anaesthesia during pregnancy

Primary outcomes

1

Description
The duration of analgesia

Timepoint
1, 3, 6, 12 and 24 hours after surgery

Method of measurement
Visual analogues Scale

Secondary outcomes

1

Description
blood Pressure

Timepoint
0,3,5,10,30,60 min and 3,6,12,24 hour after surgery

Method of measurement
BP Cuff

2

Description
Heart Rate

Timepoint
0,3,5,10,30,60 min and 3,6,12,24 hour after surgery

Method of measurement
ECG

3

Description
Nausea & Vomiting

Timepoint
The start of spinal until 24 hours after surgery

Method of measurement
Observation

Intervention groups

1

Description
Bupivacaine-Dexmedetomidine groups:10 mg hyperbaric bupivacaine plus 0.05 ml (5 µg) dexmedetomidine

Category
Treatment - Drugs

2

Description
Bupivacaine-Sufentanil groups: 10 mg hyperbaric bupivacaine plus 0.5 ml (2.5 µg) sufentanil

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Ruhani Hospital

Full name of responsible person
Dr Seyed Mozaffar Rabiee

Street address
Daneshgah Square, Ganjafrooz Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor Of Research Babol University Of Medical Sciences

Full name of responsible person
Dr Amrolah Mostafazadeh

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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
Vice-chancellor Of Research Babol 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
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Assistant Professor Of Anesthesiology

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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