

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of analgesic effect of intrathecal sufentanil-bupivacaine versus dexmedetomidine -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. Intrathecal opioid or dexmedetomidine injections are two examples of these methods. In this study the efficacy of intrathecal dexmedetomidine 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 - dexmedetomidine 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

Babool 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 dexmedetomidine -bupivacaine in cesarean delivery

Public title

Duration of analgesia effect of intrathecal sufentanil-bupivacaine versus dexmedetomidine -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/زپ

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

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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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Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

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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

Babol University Of Medical Sciences

Full name of responsible person

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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