# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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

**Country**

Iran (Islamic Republic of)

**Phone**

+98 11 1223 8296

**Email address**

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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

**City**
Babol

## 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

**Street address**
Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

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Babol

**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**
Dr Seyed Mozaffar Rabiee

**Position**
Assistant Professor Of Anesthesiology

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Dr Seyed Mozaffar Rabiee

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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*