Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

The effect of low dose Bupivacaine with fentanyl in spinal anesthesia for cesarean delivery to prevent maternal hypotension

Protocol summary

Summary

The aim of this randomized double blind clinical trial is reducing usual dose of bupivacaine for spinal anesthesia by adding fentanyl. Can be reducing common side effects of bupivacaine (hypotension), this result in an appropriate level of anesthesia in patients. 105 pregnant women (18 to 40-year-old) candidate for elective cesarean section with spinal anesthesia entered the study. Who had singleton term pregnancies in class I physical health classification of the American Society of Anesthesia (ASA).And mothers with a history of hypertension, diabetes, cardiovascular and cerebral diseases, known fetal anomaly, any kind of contraindications for spinal anesthesia and those with difficult tracheal intubation were excluded. They were randomly divided into three groups of 35 women. The first group received 10 mg of bupivacaine 0.5%, the second received 8 mg of bupivacaine 0.5% with 25 microgram of fentanyl, and the third received 8 mg of bupivacaine 0.5% with 0.4 ml of normal saline Intrathecally. Blood pressure, heart rate, sensory level, degree of motor block, pain score during operation, nausea and vomiting, time taken to recover from sensory and motor block were measured and compared in three groups during and after surgery. Our data will be analyzed using the using t-test, Mann-Whitney test and Chi-square tests. A P value <0.05 will be considered statistically significant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201704183305N8**
Registration date: **2017-04-28, 1396/02/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-04-28, 1396/02/08

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor Of Research Babol University Of Medical Sciences

Expected recruitment start date

2015-12-06, 1394/09/15

Expected recruitment end date

2016-12-05, 1395/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low dose Bupivacaine with fentanyl in spinal anesthesia for cesarean delivery to prevent maternal hypotension

Public title

The Effect Of Spinal Anesthesia Drug to Prevent Maternal Hypotention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women, candidate for elective CS, in class I physical health classification of the American Society of Anesthesia (ASA). All women had singleton term pregnancies. Exclusion criteria: Mothers with a history of hypertension, diabetes, cardiovascular and cerebral diseases, known fetal anomaly, any kind of contraindications for spinal anesthesia, patients weighing over 100 kg and those with dificult tracheal intubation.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

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

Babol University of Medical Sciences, Ganjafrooz Street, Babol

City

Babol

Postal code

47176-41367

Approval date

2015-12-06, 1394/09/15

Ethics committee reference number

MUBABOL.REC.1394.232

Health conditions studied

1

Description of health condition studied

Maternal hypotension

ICD-10 code

O26.5

ICD-10 code description

maternal hypotension syndrome

Primary outcomes

1

Description

Maternal blood presure

Timepoint

Maternal blood pressure was monitored and recorded every two minutes for the first 15 minutes following spinal anesthesia, and then every 5 minutes until completion of surgery.

Method of measurement

Non invasive blood presure cuff

Secondary outcomes

1

Description

Sensory level and motor block

Timepoint

After spinal anesthesia

Method of measurement

Sensory level was assessed using the tip of a needle sterilized with alcohol cotton, and motor block was assessed and recorded using Bromage Scale (BS) (BS=0, full knee and foot flexion; BS=1, ability to move knee; BS=2, ability to move feet only; BS=3, full motor block).

2

Description

pain

Timepoint

Pain level during surgery

Method of measurement

VAS (Visual analogues Scale)

3

Description

Return of sensory and motor block

Timepoint

After Surgery

Method of measurement

Examination, Question & Observation

Intervention groups

1

Description

Control group: 10 mg 0.5% bupivacaine was injected into subarachnoid space.

Category

Prevention

2

Description
Intervention Group1: 8 mg of bupivacaine 0.5 with 25 micrograms of fentanyl was injected into subarachnoid space.
Category
Prevention

3

Description
Intervention Group2: 8 mg of bupivacaine 0.5% with 0.4 micrograms of Normal saline was injected into subarachnoid space
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Rouhani Hospital of Babol
Full name of responsible person
Dr Hakimeh Alereza Amiri
Street address
Rouhani Hospital of Babol, Ganjafroz St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor research for Babol University of Medical Sciences
Full name of responsible person
Dr. Ali Akbar Moghadamnia
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Babol University Of Medical Sciences, Ganjafrooz street, Babol
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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 research for 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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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