Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Compare the effects of intrathecal hyperbaric Bupivacaine injected at different doses in combination with a fixed dose of Sufentanil in Cesarean section

Protocol summary

Summary

For compare the effects of intrathecal hyperbaric Bupivacaine injected at different doses in combination with a fixed dose of Sufentanil in Cesarean section, in a double blind clinical trial after obtaining the consent of the patients, 105 patients undergoing caesarean section randomly using Blocks randomized into three groups: A (8mg bupivacaine 0.5% hyperbaric), B (9mg bupivacaine 0.5% hyperbaric) and C (10mg bupivacaine 0. 5% hyperbaric) at each 2.5 micg as adjuvant added Sufentanil, and we split these drugs for spinal anesthesia may apply. The maximum Sensory and Motor Block, Quality of Analgesia during surgery and complications (Nausea, Vomiting, Hypotension, Bradycardia, and Itching) determined in all three groups, we recorded and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010931852N1**
Registration date: **2017-03-11, 1395/12/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-03-11, 1395/12/21

Registrant information

Name

Mahzad Alimian

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chanceler for research, Iran university of medical sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-01-29, 1395/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effects of intrathecal hyperbaric Bupivacaine injected at different doses in combination with a fixed dose of Sufentanil in Cesarean section

Public title

Compare the effects of intrathecal hyperbaric Bupivacaine injected at different doses in combination with a fixed dose of Sufentanil in Cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Not Preeclampsia; ASA<3; Gestational age>36weeks; Not twain; Height>150cm; Not addiction; Not spinal block contraindication Exclusion criteria: Spinal block technical problems

Age

No age limit

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
Ethic Committee of Iran University of Medical Science
Street address
Hemmat highway
City
Tehran
Postal code
Approval date
2015-04-26, 1394/02/06
Ethics committee reference number
IR.IUMS.REC.1394.۱۰۵/۴۶۸/د

Health conditions studied

1

Description of health condition studied
Pregnancy
ICD-10 code
082
ICD-10 code description
Caesarean section

Primary outcomes

1

Description
Sensory block level
Timepoint
Every 5 minutes
Method of measurement
Pin prick test

2

Description
Motor block level
Timepoint
Every 5 minutes
Method of measurement
Bromage score

Secondary outcomes

1

Description
Nausea
Timepoint
Operation time and Recovery
Method of measurement
Patient statement

2

Description
Vomiting
Timepoint
Operation time and Recovery
Method of measurement
Patient status

3

Description
Itching
Timepoint
Operation time and Recovery
Method of measurement
Patient statement

4

Description
Hypotention
Timepoint
Every 5 minutes
Method of measurement
Non Invasive Blood Pressure measuring

5

Description
Bradycardia
Timepoint
Every 5 minutes
Method of measurement
Pulseoxymetery

Intervention groups

1

Description
A: Intratechal injection of 8 mg hyperbaric Bupivacaine with 2.5 micg Sufentanil
Category
Treatment - Drugs

2

Description
B: Intratechal injection of 9 mg hyperbaric Bupivacaine with 2.5 micg Sufentanil
Category
Treatment - Drugs

3

Description
C: Intratechal injection of 10 mg hyperbaric Bupivacaine with 2.5 micg Sufentanil
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool akram Hospital
Full name of responsible person
Alireza Rajabi
Street address
Shahrara ave
City
Tehran

2

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Alireza Rajabi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for search,Iran University of Medical Science
Full name of responsible person
Alimian Mah zad
Street address
Hemmat Highway
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for search,Iran 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

Contact
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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