

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 chancellor 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.1394.1.0/468/3

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

Pulseoxymetry

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

Street address

Vali e asr sq

City

Tehran

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

City

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

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Rajabi Alireza

Position

Medical Assistant

Other areas of specialty/work

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Web page address**Fax****Email****Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

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Position

Medical Assistant

Other areas of specialty/work**Street address**

Hemmat Highway

City

Tehran

Postal code**Phone****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