

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effects of intrathecal fentanyl, pethidine or placebo added to lidocaine and epinephrine on the duration of postoperative analgesia in spinal anesthesia for elective cesarean delivery.

Protocol summary

Summary

The aim of this study is comparison of the effects of intrathecal fentanyl, pethidine or placebo added to lidocaine and epinephrine on the duration of postoperative analgesia in spinal anesthesia for elective cesarean delivery. This study will be performed on 195 pregnant women in Rasht Al-Zahra hospital. After signing the informed consent from study participants, the women will be randomly divided into three groups of 65 persons. The first group (Intervention group) will be anesthetized under spinal anesthesia with 25 microgram fentanyl and 75 mg lidocaine and 0.02mg epinephrine and the second group (intervention group) with 25mg pethidine and 75 mg lidocaine and 0.02mg epinephrine and the third group (control group) with 1.5ml normal saline and 75mg lidocaine and 0.02mg epinephrine. Any person who involved for outcome evaluations in this study, have no information about prescribed medications. for having ability to treat the probable complications, the major anesthesiologist will be aware of the kind of drug. Preoperative heart rate, blood pressure, O2 saturation, respiratory rate, level of consciousness, nausea and vomiting will be monitored. After birth of the infant, APGAR score will be measured. After ending the operation, every 1hour in the first 6hours and then every 2hours for the next 18hours about the analgesia according to VAS score (0 to 10) will be asked from mother and if pain or the other probable complications present, treating will be started.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201128677N2**
Registration date: **2012-01-19, 1390/10/29**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-19, 1390/10/29

Registrant information

Name

Farnoush Farzi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 5624

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Guilan University of Medical Sciences

Expected recruitment start date

2011-11-01, 1390/08/10

Expected recruitment end date

2012-10-31, 1391/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of intrathecal fentanyl, pethidine or placebo added to lidocaine and epinephrine on the duration of postoperative analgesia in spinal anesthesia for elective cesarean delivery.

Public title

Comparison the effects of intrathecal fentanyl, pethidine or placebo added to lidocaine and epinephrine on the duration of postoperative analgesia in spinal anesthesia for elective cesarean delivery.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: being candidate for elective cesarean delivery; ASA class 1&2 and signing informed consent.
Exclusion criteria: addiction; contraindications for spinal anesthesia; hypersensitivity to opioids and local anesthetics; gestational hypertension; chronic itching; multi parity; having two or more surgery together and the duration of operation longer than 1.5 hours.

Age

From **15 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **195**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee Guilan University of Medical Sciences

Street address

Melat st, Namjoo Ave

City

Rasht

Postal code

Approval date

2011-10-31, 1390/08/09

Ethics committee reference number

504

Health conditions studied

1

Description of health condition studied

Pregnancy, childbirth and the puerperium

ICD-10 code

O74.8

ICD-10 code description

Other complications of anaesthesia during labour and delivery

Primary outcomes

1

Description

Determination of effect of added fentanyl or pethidine in compare with normal saline to lidocaine and epinephrine on the duration of postoperative analgesia in spinal anesthesia for elective cesarean delivery.

Timepoint

After delivery, then every 1 hour in the first 6 hours and every 2 hours in the latter 18 hours

Method of measurement

By using VAS score with a scaled liner with scaling from 0 to 10

Secondary outcomes

1

Description

Determination of frequency of blood pressure decline after delivery in three groups.

Timepoint

During delivery, then every 1 hour in the first 6 hours and every 2 hours in the latter 18 hours

Method of measurement

Noninvasive blood pressure measuring

2

Description

Determination of frequency of nausea in three groups

Timepoint

During delivery, then every 1 hour in the first 6 hours and every 2 hours in the latter 18 hours

Method of measurement

Questioning from patient(having or not)

3

Description

Determination of frequency of vomiting in three groups

Timepoint

During delivery, then every 1 hour in the first 6 hours and every 2 hours in the latter 18 hours

Method of measurement

Observation the patient

4

Description

Determination of infant's APGAR in three groups

Timepoint

After infant's birth and every 5 minute till the 20th minute

Method of measurement

APGAR score

5**Description**

Determination of frequency of itching in three groups

Timepoint

During delivery, then every 1 hour in the first 6 hours and every 2 hours in the latter 18 hours

Method of measurement

Questioning from patient(having or not)

6**Description**

Comparison of frequency of sedation in three groups

Timepoint

During delivery, then every 1 hour in the first 6 hours and every 2 hours in the latter 18 hours

Method of measurement

Observation the patient

7**Description**

Determination of frequency of respiratory depression in three groups

Timepoint

During delivery, then every 1 hour in the first 6 hours and every 2 hours in the latter 18 hours

Method of measurement

Respiratory rate <8 and o2 saturation with pulse oxymeter

Intervention groups**1****Description**

Prescription of 25 microgram fentanyl and 75 mg lidocaine and 0.02mg epinephrine to intervention group.

Category

Treatment - Drugs

2**Description**

Prescription 25 mg pethidine and 75 mg lidocaine and 0.02mg epinephrine to intervention group.

Category

Treatment - Drugs

3**Description**

Prescription of 1.5 ml normal saline and 75 mg lidocaine and 0.02mg epinephrine to control group

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Al-Zahra Hospital

Full name of responsible person

Farnoush Farzi

Street address

Namjoo street

City

Rasht

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research, Guilan University of Medical Sciences

Full name of responsible person

Dr. Abdolrasol Sobhani

Street address

Mellat St., Namjoo Ave.

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research, Guilan 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**

Guilan University of Medical Sciences

Full name of responsible person

Farnoush Farzi

Position

Anesthesiologist

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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