Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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

Email address

farnoush_farzi@gums.ac.ir

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
Other areas of specialty/work
Street address
Reproduction Health Research Center, Al-Zahra hospital, Namjo street
City

Rasht
Postal code
Phone
+98 13 1322 5624
Fax
Email
farnoush_farzi@gums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Farnoush Farzi
Position
Anesthesiologist
Other areas of specialty/work
Street address
Reproduction Health Research Center, Al-Zahra hospital, Namjo street
City
Rasht
Postal code
Phone
+98 13 1322 5624
Fax
Email
farnoush_farzi@gums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Reproduction Health Research Center
Full name of responsible person
Seyedeh Maryam Mousavi Chahardeh
Position
Obstetrics
Other areas of specialty/work
Street address
Al_Zahra Hospital, Namjoo Street
City
Rasht
Postal code
4144656839
Phone
+98 13 1322 5624
Fax
+98 13 1322 5624
Email
maryammosavi1363@yahoo.com
Web page address

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