

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison the effects of intrathecal Fentanyl and Bupivacaine with Sufentanyl plus Bupivacaine on duration of post-operative pain and side effect in elective caesarean section in alzahra hospital

Protocol summary

Summary

The aim of this study is comparison of effects of intrathecal Fentanyl and Bupivacaine with Sufentanyl plus Bupivacaine on duration of post-operative pain and side effect in elective caesarean section. Inclusion criteria: ASA class 1 & 2; Age between 15-45 years old; Height between 150-170 centimeters Exclusion criteria: Time of operation lasts more than 1.5 hours; Intraoperative bleeding more than 1500 cc; the patient's inability to keep immobility during blocks. 90 patients randomly divided in 3 groups. All patients undergoing intrathecal anesthesia with Bupivacaine. Additionally group F receive Fentanyl, group S receive Sufentanyl and group P injected placebo. During surgery patients will monitor by pulse oximetry, non-invasive barometer and ECG. Blood pressure, heart rate, nausea, vomiting, itching, drowsiness, respiratory depression and Apgar score, sensory block level, motor block level; recovery of sensory block to T10, reversible motor block, pain and shivering and patient satisfaction assessment is evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506068677N6**
Registration date: **2015-06-29, 1394/04/08**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-06-29, 1394/04/08

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

Guilan University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of intrathecal Fentanyl and Bupivacaine with Sufentanyl plus Bupivacaine on duration of post-operative pain and side effect in elective caesarean section in alzahra hospital

Public title

The effects of intrathecal Fentanyl and Bupivacaine with Sufentanyl plus Bupivacaine on duration of post-operative pain and side effect in elective caesarean section in alzahra hospital

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ASA class 1 & 2: Age between 15-45 years old: Height between 150-170 centimeters
Exclusion criteria: The time of operation lasts more than 1.5 hours; Intraoperative bleeding more than 1500 cc; the patient's inability to keep immobility during blocks

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Ethics committee of Guilan University of Medical Sciences

Street address

Namjoo Avenue

City

Rasht

Postal code

4193893345

Approval date

2015-05-12, 1394/02/22

Ethics committee reference number

IR.GUMS.REC.1394.23

Health conditions studied

1

Description of health condition studied

Cesarean section

ICD-10 code

O82.9

ICD-10 code description

Delivery by caesarean section, unspecified

Primary outcomes

1

Description

Painless duration after surgery

Timepoint

The first 15 minutes every 3 minutes, 45 minutes later every 15 minutes, to 4 hours every 30 minutes, 3 hours later every 1 hour and 16 hours later every 4 hours

Method of measurement

According VAS score

2

Description

Using a pressure gauge

Timepoint

Since intrathecal anesthesia to birth every 3 minutes and then every 5 minutes

Method of measurement

Using pressure pump

3

Description

Neonate APGAR

Timepoint

Minute 1 and 5 According

Method of measurement

APGAR criteria

4

Description

Complications

Timepoint

The first 15 minutes every 3 minutes, 45 minutes later every 15 minutes, to 4 hours every 30 minutes, 3 hours later every 1 hour and 16 hours later every 4 hours

Method of measurement

According patient's history

5

Description

Sensory block level and recovery of sensory block to T10

Timepoint

30 and 60 seconds after injection

Method of measurement

Using Pin prick method

6

Description

Motor block level and recovery of motor block

Timepoint

30 and 60 seconds after injection

Method of measurement

Using Bromage scale

Secondary outcomes

empty

Intervention groups

1

Description

Injection 12.5 milligrams Bupivacaine and 25 microgram Fentanyl

Category

Treatment - Drugs

2

Description

Injection 12.5 milligrams Bupivacaine and 2.5 milligram Sufentanyl

Category

Treatment - Drugs

3

Description

Injection 12.5 milligrams Bupivacaine and 0.5 milliliters normal saline

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Dr. Farnoosh Farzi

Street address

Namjoo Avenue

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Guilan University of Medical Sciences

Full name of responsible person

Abtin Heidarzadeh

Street address

Shahid Beheshti Freeway

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 of 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

Farnoosh Farzi

Position

Anesthesiologist

Other areas of specialty/work

Street address

Alzahra hospital, Namjoo Avenue

City

Rasht

Postal code

4193713194

Phone

+98 133229524

Fax

+98 13 3334 5132

Email

arcguilan1392@gmail.com;

Farnoush_farzi@gmail.com

Web page address

www.arc.gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Farnoosh Farzi

Position

Anesthesiologist

Other areas of specialty/work

Street address

Alzahra hospital, Namjoo Avenue

City

Rasht

Postal code

4139638459

Phone

+98 13 3336 8534

Fax

+98 13 3334 5132

Email

arcguilan1392@gmail.com;
farnoush_farzi@gmail.com

Web page address

www.arc.gums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Hedyeh Nemati

Position

Medical laboratory Sciences Technician/ Bachelor's
Degree

Other areas of specialty/work

Street address

Poursina Hospital, Dr. Heshmat st.

City

Rasht

Postal code

4193713194

Phone

+98 13 3336 8534

Fax

+98 13 3334 5132

Email

nematihedieh@gmail.com

Web page address

www.arc.gums.ac.ir

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