

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparing the intrathecal effects of sufentanil, fentanyl, and intravenous apotel as adjuvants to bupivacaine on duration, side effects, and efficiency of spinal anesthesia in elective cesarean section

Protocol summary

Study aim

Comparison of Intrathecal Bupivacaine with Placebo and Fentanyl and Sufentanyl and Bupivacaine on Duration of Anesthesia and Complications of Spinal Anesthesia in elective Cesarean Section

Design

Randomized Clinical Trial phase II-III with 105 patients, Patients are assigned to each group according to the table which is derived from randomization.org after fulfilling the conditions for entering the study.

Settings and conduct

In Hafez hospital, Shiraz, patients in group one received 10 mg bupivacaine 0.5%, 2 micrograms of sufentanil, 0.1 ml of normal saline. patients in group 2two received 10 mg bupivacaine 0.5%, 10 micrograms of fentanyl, 0.3 ml of normal saline. patients in group three received 10 mg bupivacaine 0.5%, the infusion of 1 gr apotel, 100 micrograms of fentanyl, and 5 mg of morphine diluted in 200 cc normal saline.

Participants/Inclusion and exclusion criteria

Inclusion Criteria:Term pregnancy, ASA I-II, Elective cesarean section. Exclusion criteria: Localized infection in the lumbar region, Use of anti-platelet and anticoagulant, Allergy to the local anesthetics, Addiction to narcotics and nicotine ,Hypovolemic shock ,Diabetes ,Renal failure ,Coagulation disorder, Liver disease, Heart diseases .

Intervention groups

Intervention group1: patients received 10 mg bupivacaine 0.5%, 2 micrograms of sufentanil, 0.1 ml of normal saline, and 200 cc normal saline as placebo intravenously after the umbilical cord removal.
Intervention group 2: patients received 10 mg bupivacaine 0.5%, 10 micrograms of fentanyl, 0.3 ml of normal saline, and 200 cc normal saline as placebo intravenously after the umbilical cord removal.
Intervention group3: patients received 10 mg bupivacaine 0.5%, the infusion of 1 gr apotel, 100

micrograms of fentanyl, and 5 mg of morphine diluted in 200 cc normal saline.

Main outcome variables

Duration of sensory block, duration of motor block and pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N101**

Registration date: **2020-07-28, 1399/05/07**

Registration timing: **prospective**

Last update: **2020-07-28, 1399/05/07**

Update count: **0**

Registration date

2020-07-28, 1399/05/07

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-02, 1399/05/12

Expected recruitment end date

2020-10-01, 1399/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the intrathecal effects of sufentanil, fentanyl, and intravenous apotel as adjuvants to bupivacaine on duration, side effects, and efficiency of spinal anesthesia in elective cesarean section

Public title

Comparison of the effects of spinal injection drugs on the duration of spinal anesthesia, complications and effect of spinal anesthesia in cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Term pregnancy Age 20 to 30 years Weight 50 - 100 kg Height between 150 -180 cm ASA I-II Elective cesarean section

Exclusion criteria:

Patient refusal Localized infection in the lumbar region Use of anti platelet and anticoagulant Allergy to the local anesthetics Addiction to narcotics and nicotine Hypovolemic shock Diabetes Renal failure Coagulation disorder Liver disease Heart diseases History of seizures or any neurological disease, Hypertension Preeclampsia Fetal anomaly, (IUGR), improper growth of the fetus in the uterus, Hemoglobin less than 8, Multiple pregnancies, Non- vertex position

AgeFrom **20 years** old to **30 years** old**Gender**

Female

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **105****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients will be allocated into intervention and control groups by block randomization using sealedenvelope.com site. This will randomly generate a sequence of 35 blocks,3 patients in each.And patients will be placed in each of the three groups according to the randomization list after applying the inclusion criteria.

Blinding (investigator's opinion)

Not 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 Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2019-09-02, 1398/06/11

Ethics committee reference number

IR.SUMS.MED.REC.1398.383

Health conditions studied**1****Description of health condition studied**

cesarean section

ICD-10 code

O82

ICD-10 code description

Encounter for cesarean delivery without indication

Primary outcomes**1****Description**

Sensory Block

Timepoint

Duration of sensory block

Method of measurement

pin-prick

2**Description**

Motor block

Timepoint

Duration of motor block

Method of measurement

modified Bromage Scale

3**Description**

Pain

Timepoint

Postoperative

Method of measurement

visual analog score

Secondary outcomes

empty

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

Intervention group1:patients received 10 mg bupivacaine 0.5%, 2 micrograms of sufentanil, 0.1 ml of normal saline , and 200 cc normal saline as placebo intravenously after the umbilical cord removal.

Category

Prevention

2**Description**

Intervention group 2: patients received 10 mg bupivacaine 0.5%, 10 micrograms of fentanyl, 0.3 ml of normal saline, and 200 cc normal saline as placebo intravenously after the umbilical cord removal.

Category

Prevention

3**Description**

Intervention group3:patients received 10 mg bupivacaine 0.5% , the infusion of 1 gr apotel, 100 micrograms of fentanyl, and 5 mg of morphine diluted in 200 cc normal saline.

Category

Prevention

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

Hafez Hospital

Full name of responsible person

Reza Jouybar

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 9531

Email

Hafez@sums.ac.ir

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

Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

Street address

Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

masihifarzaneh@yahoo.com

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Reza Jouybar

Position

Cardio-anesthesiologist

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

joybarr@sums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Reza Jouybar

Position

Cardio-anesthesiologist

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

joybarr@sums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

MS in English Teaching, BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

5th floor, Mohammad Rasoul Allah Research Tower, Khalili Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

masihifarzaneh@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available