Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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
Age
From **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