Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison the effect of composition of fentanyl or interathecal suffentanil with 0.5 hyperbaric bupivacaine in spinal anesthesia in elective cesarean patients

Protocol summary

Study aim
Evaluation the effect of fentanyl or sufentanil composition with 0.5 hyperbaric bupivacaine in spinal anesthesia

Design
Clinical trials with control group; community based and pragmatic; with parallel groups; one-way blinded; randomized

Settings and conduct
In this study, 90 patients with elective cesarean section referred to Ali ibn Abitaleb Hospital in Zahedan and eligible for inclusion in the study are selected. Participants are randomly divided into three groups. The first intervention group (fentanyl) will receive 20 µg fentanyl plus 0.5% hyperbaric bupivacaine and the second group (sufentanil) will receive 5.2 µg sufentanil plus 0.5% hyperbaric bupivacaine and the control group (placebo) will receive 0.5 cc distilled water with no additional opioids. The analgesic effects will be evaluated and compared based on 4 grades.

Participants/Inclusion and exclusion criteria
Primigravida; ASA class one and two; Caesarean section due to cephalopelvic disproportion

Intervention groups
The first intervention group (Fentanyl) receiving 20 µg fentanyl plus 0.5% hyperbaric bupivacaine; the second intervention group (sufentanil) receiving 5.2 µg sufentanil plus 0.5% hyperbaric bupivacaine; the control group (placebo) receiving 0.5 cc distilled water with no additional opioids

Main outcome variables
Quality of analgesia; duration of effective analgesia; duration of patient discharge

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171109037340N1**
Registration date: **2018-03-10, 1396/12/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-10, 1396/12/19**
Update count: **0**

Registration date
2018-03-10, 1396/12/19

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 54 3329 5799
Email address
dr.arefpour@zaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-02-08, 1395/11/20

Expected recruitment end date
2018-05-10, 1397/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effect of composition of fentanyl or interathecal suffentanil with 0.5 hyperbaric bupivacaine

in spinal anesthesia in elective cesarean patients

Public title
Evaluation of the effect of fentanyl or sulfentanil on spinal anesthesia in cesarean section
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Term pregnancy Primigravida ASA class 1 and 2 Cesarean section due to cephalopelvic disproportion
Exclusion criteria:
spinal anesthesia contraindication Gestational hypertension Gestational diabetes Placenta previa
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Block
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zahedan Medical University of Science
Street address
Ethics Committee of Zahedan Medical University of Science, Zahedan Medical University of Science, Dr.Hesabi Square, Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2017-01-23, 1395/11/04
Ethics committee reference number
IR.ZAUMS.REC.1395. 52

Health conditions studied

1

Description of health condition studied
Cesarean section
ICD-10 code
O75.82
ICD-10 code description
Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks gestation, with delivery by (planned) cesarean section

Primary outcomes

1

Description
Analgesia quality
Timepoint
Immediately after drug injection
Method of measurement
Based on 4 grades; Excellent: During the procedure, patients feel comfortable with no complainment. Good: brief discomfort with no need of additional medication. Moderate: Unpleasant but controllable with additional medication such as phenthanyl, propofol, dormicom and the like. Poor: Inability to control even with an additional drug

2

Description
The duration of effective analgesia
Timepoint
The interval between the initiation of drug administration in each group until the first request of analgesia by patients
Method of measurement
1-awake and anxious; 2- awake and calm; 3- sleepy but easily awake; 4- sleepy but not easily awake.

3

Description
Duration of discharge
Timepoint
The interval between the initiation of drug administration in each group until the time of discharge from hospital
Method of measurement
Day

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: receiving 20 µg fentanyl plus 0.5% hyperbaric bupivacaine
Category
Treatment - Drugs

2

Description
Second intervention group: receveing 5.2 µg sufentanil plus 0.5% hyperbaric bupivacaine
Category
Treatment - Drugs

3

Description
Control group: receiving 0.5 cc distilled water without any additional opioid
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali ebn abi talib Zahedan Hospital
Full name of responsible person
Dr Shahram Borjian Boroujeni
Street address
Zahedan Ali-ebn Abi Talib Hospital, Salamat Blvd, Dr.Hesabi Sq., Zahedan
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Dr.borjian@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Dr Mohsen Taheri
Street address
Vice chancellor for research, Zahedan University of Medical Sciences, Zahedan
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dr.taheri@zaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Zahra Arefpour
Position
Anesthesiology Residence
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Zahedan Ali-ebn Abi Talib Hospital, Salamat Blvd, Dr.Hesabi Sq., Zahedan
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person

Dr Shahram Borjian Boroujeni

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Operation room, Ali-ebn Abi Taleb Hospital, Hesabi Sq., Daneshgah Ave., Zahedan, Sistan and Balouchestan

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Zahra Arefpour

Position

Anesthesia Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

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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