

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Comparison the effect of composition of fentanyl or interathecal sufentanil 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 sufentanil 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: receiving 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

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Phone

+98 54 3329 5744

##### Email

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

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

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##### Phone

+98 54 3329 5744

##### Email

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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##### Province

Sistan-va-Balouchestan

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##### Email

Dr.arefpour@zaums.ac.ir

## 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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Zahra Arefpour

**Position**

Anesthesia Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

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

**City**

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**Phone**

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**Email**

Dr.arefpour@zaums.ac.ir

**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