

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 phentanyl, 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

9816743463

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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5744

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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5730

Email

Dr.borjian@zaums.ac.ir

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

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5731

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