

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of the effect of adding sufentanil to ropivacaine 0.5% and sufentanil to bupivacaine 0.5% on analgesia and chills during and after surgery in subjects undergoing elective cesarean section

Protocol summary

Study aim

Comparison of the effect of adding sufentanil to ropivacaine 0.5% and sufentanil to bupivacaine 0.5% on analgesia and chills during and after surgery in subjects undergoing elective cesarean section

Design

This study will be a double-blind randomized clinical trial with factorial groups on 60 patients referred to Motahhari Hospital in Jahrom who are undergoing cesarean section. Patients participating in the study will be divided into two groups by tossing coins.

Settings and conduct

Patients referred to Motahhari Hospital in Jahrom who will undergo cesarean section will be included in the study. Patients participating in the study will be divided into two groups of bupivacaine and ropivacaine by throwing coins. The study participant, researcher, and data collector will be unaware of the type of drug used.

Participants/Inclusion and exclusion criteria

All patients referred to Motahhari Hospital in Jahrom who underwent cesarean section and expressed their consent to participate in the study and did not meet the exclusion criteria.

Intervention groups

The intervention group 1: received 15 mg of bupivacaine and sufentanil intrathecally. Intervention group 2: received 15 mg of ropivacaine and sufentanil intrathecally.

Main outcome variables

Pain, chills

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130926014779N7**

Registration date: **2020-08-29, 1399/06/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-29, 1399/06/08**

Update count: **0**

Registration date

2020-08-29, 1399/06/08

Registrant information

Name

Navid Kalani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5426 4192

Email address

k.navid@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-31, 1398/10/10

Expected recruitment end date

2020-11-30, 1399/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of adding sufentanil to ropivacaine 0.5% and sufentanil to bupivacaine 0.5% on analgesia and chills during and after surgery in subjects undergoing elective cesarean section

Public title

The effect of adding sufentanil to ropivacaine 0.5% and sufentanil to bupivacaine 0.5% on analgesia and chills during and after surgery in subjects undergoing elective cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Interest in participating in the study No chronic pain and cancer No hearing or verbal impairment Hemodynamic stability No infection at the site of needle entry Not High intracranial pressure No coagulation disorders

Exclusion criteria:

People who need medication or action other than routine care during surgery to relieve complications and reduce pain.

Age

From **16 years** old to **45 years** old

Gender

Female

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients participating in the present study were divided into two groups by coin toss.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding in the present study, the double-blind method is used in such a way that 1- the person who participates in the study 2- the person who reviews the results and 3- the person who performs the injections information are unaware of which patients have received ropivacaine and which patients have received sufentanil and bupivacaine.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Jahrom University of Medical Sciences

Street address

School of Medicine, Motahhari Blvd., Jahrom

City

Jahrom

Province

Fars

Postal code

716775522

Approval date

2020-02-17, 1398/11/28

Ethics committee reference number

IR.JUMS.REC.1398.110

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

Pain

Timepoint

Before the spinal, after the spinal and during the change of position of the patient and then every 15 minutes to the first hour and also during the entry into recovery and when leaving the recovery and finally three and six hours after the operation

Method of measurement

Pain assessment ruler

2

Description

Shivering

Timepoint

Before the spinal, after the spinal and during the change of position of the patient and then every 15 minutes to the first hour and also during the entry into recovery and when leaving the recovery and finally three and six hours after the operation

Method of measurement

Shivering scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: received 15 mg bupivacaine + 25 µg sufentanil intrathecally.

Category

Treatment - Drugs

2

Description

Intervention group 2: received 15 mg ropivacaine + 25 µg sufentanil intrathecally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari Hospital

Full name of responsible person

Navid Kalani

Street address

Jahrom, Motahhari Boulevard, Motahhari Hospital

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k.navid@jums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Solh Ju Kavos

Street address

Jahrom, Shahid Motahari Boulevard, Jahrom University of Medical Sciences, Vice Chancellor for Research

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k.navid@jums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Nahid Tadayon

Position

medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Navid Kalani

Position

Research staff

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Email

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Nahid Tadayon

Position

medical student

Latest degree

Medical doctor

Other areas of specialty/work

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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

No - There is not 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