Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effectiveness of dexmedetomidine with sufentanil in adding intrathecal ropivacaine on analgesia in the elective cesarean section - A Randomized Double-Blind Clinical Trial

Protocol summary

Study aim

Determination of the effectiveness of dexmedetomidine with sufentanil in intrathecal ropivacaine supplementation on analgesia in the elective cesarean section.

Design

This study is a double-blinded clinical trial. One hundred and thirty-six patients will be selected in an available method and simple randomly assigned to two intervention groups. Then the intervention is done. After the surgery, the pain and duration of analgesia and headaches are measured by means of the VAS tool and recorded in the checklist, and the two groups are compared with each other.

Settings and conduct

The study will be performed in the gynecology ward of Imam Reza Hospital in Kermanshah. Randomization of patients between the first intervention group (dexmedetomidine /ropivacaine) and the second group(sufentanil /ropivacaine) is done using random allocation software. In this software, the total sample size and number of nodes are entered into the software. The output of Shalam software is a list that randomly distributes patients in groups 1 and 2.

Participants/Inclusion and exclusion criteria

Inclusion criteria include singleton and term pregnant women aged 18 to 45 years, having a body mass of 18 to 30 with ASA class I. Exclusion criteria include having any underlying disease, history of allergy to local anesthetic, dexmedetomidine and sufentanil, coagulation disorders, local skin infection at the site of spinal anesthesia, surgery Emergency cesarean section, and cases where we have to undergo general anesthesia during surgery.

Intervention groups

In the first intervention group, 5 micrograms of dexmedetomidine and 12.5 micrograms of isobaric ropivacaine 0.5%, and in the second intervention group, 5 micrograms of sufentanil with 12.5 micrograms of isobaric ropivacaine 0.5% isobars are injected intrathecally into the subarachnoid space.

Main outcome variables

Time of onset of analgesia, duration of analgesia.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201212049688N1**
Registration date: **2021-05-18, 1400/02/28**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-18, 1400/02/28**
Update count: **0**

Registration date

2021-05-18, 1400/02/28

Registrant information

Name

haniyeh azadifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 4618

Email address

haniyeh.azadifar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-19, 1400/01/30

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effectiveness of dexmedetomidine with sufentanil in adding intrathecal ropivacaine on analgesia in the elective cesarean section - A Randomized Double-Blind Clinical Trial

Public title
Evaluation of the effectiveness of dexmedetomidine with sufentanil in combination with intrathecal ropivacaine on analgesia in cesarean section
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
singleton and term pregnant women 18 to 45 years. Having a body mass of 18 to 30. Patients referred for elective cesarean section, who are classified as Class I according to the American Society of Anesthesiology (A.S.A).
Exclusion criteria:
Having any underlying disease History of allergy to local anesthetic Coagulation disorders, local skin infection at the site of spinal anesthesia Surgery Emergency cesarean section Cases where we have to undergo general anesthesia during surgery
Age
From **18 years** old to **30 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **136**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of patients between the first intervention group (dexmedetomidine with ropivacaine) and the second intervention group(sufentanil with ropivacaine) is done using random allocation software. In this software, the total sample size and number of nodes are entered into the software. The output of Shalam software is a list that randomly distributes patients in groups 1 and 2. Patients are divided into two groups according to the time of referral according to the list of the mentioned group until the end of sampling.
Blinding (investigator's opinion)
Double blinded
Blinding description
The person in charge of injecting drugs is not aware of the allocation of individuals to groups. The person evaluating the patients is also unaware of the allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Kermanshah University of Medical Science
Street address
Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.Kermashah,Iran
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Approval date
2021-02-16, 1399/11/28
Ethics committee reference number
IR.KUMS.REC.1399.1136

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
Time of onset of analgesia.
Timepoint
1,2,4,6,8,10,12,16,20,24 hours after the end of the surgery.
Method of measurement
With Visual Analog Scale.

2

Description

duration of analgesia

Timepoint

1,2,4,6,8,10,12,16,20,24 hours after the end of the surgery.

Method of measurement

With Visual Analog Scale.

Secondary outcomes

1

Description

Blood pressure changes

Timepoint

In minutes 1,5,10,15,20,25,30,60 after injection

Method of measurement

By barometer and registration in the relevant forms.

2

Description

Nausea

Timepoint

After the intervention

Method of measurement

By asking the patient questions and observing objectively.

3

Description

Vomiting

Timepoint

After the intervention

Method of measurement

By asking the patient questions and observing objectively.

4

Description

Headache

Timepoint

After the intervention

Method of measurement

By Visual Analog Scale.

5

Description

heart rate

Timepoint

In minutes 1,5,10,15,20,25,30,60 after injection

Method of measurement

By pulse oximeter.

6

Description

respiratory distress

Timepoint

After the intervention

Method of measurement

By objective observation.

Intervention groups

1

Description

Intervention group: In the first intervention group, 5 micrograms of dexmedetomidine and 12.5 micrograms of isobaric ropivacaine 0.5% are injected intrathecally into the subarachnoid space.

Category

Treatment - Drugs

2

Description

Intervention group: In the second intervention group, 5 micrograms of sufentanil with 12.5 micrograms of isobaric ropivacaine 0.5% isobars are injected intrathecally into the subarachnoid space.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital-Kermanshah

Full name of responsible person

Hanieh Azadifar

Street address

Next to the medical school, the end of Parstar Blvd, Kermanshah , Iran.

City

Kermanshah

Province

Kermanshah

Postal code

674277533

Phone

+98 83 3427 6300

Email

hooman.rafiee@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Taleghani Hospital, Taleghani Street, Kermanshah, Iran.

City

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6715847167
Phone
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fnajafi@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Hanieh Azadifar
Position
Anesthesia resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Next to the medical school, the end of Parstar Blvd, Kermanshah, Iran.
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Hanieh Azadifar
Position
Anesthesia resident
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document

Data on demographic information and the onset and duration of analgesia in patients are shared as anonymous codes.

When the data will become available and for how long

Data access to 2022 is possible.

To whom data/document is available

Access to the data will be open to those interested in research

Under which criteria data/document could be used

Giving data for scientific use is permissible without bias

From where data/document is obtainable

Can be contacted by .

What processes are involved for a request to access data/document

About a week from the time of the first email call.

Comments