Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The comparison of Addition of Dexmedetomidine and Fentanyl in Spinal Anesthesia with Bupivacaine in Cesarean Section

Protocol summary

Study aim

Comparison of the efficacy of adding dexmedetomidine and fentanyl in spinal anesthesia with bupivacaine in cesarean section.

Design

In the intervention group, intrathecal injection of 3 µg dexmedetomidine with 12.5 mg bupivacaine and in the control group intravenous injection of 25 µg fentanyl with 12.5 mg bupivacaine. The sample size is 40 people in each group by simple random sampling and three blind sampling

Settings and conduct

This study was carried out on 80 pregnant women with II and ASA I candidates for elective elective cesarean section after confirmation of research consent from Mashhad University of Medical Sciences. In the intervention group, intrathecal injection of 3 µg dexmedetomidine with 12.5 mg bupivacaine and in the control group intravenous injection of 25 µg fentanyl with 12.5 mg bupivacaine. The number of blinds is three blind and those who are blind are the study subjects, evaluators and analysts.

Participants/Inclusion and exclusion criteria

In clusion criteria: mothers of ASA I, II, 18 to 45 years of age and candidate for elective cesarean section. Exclusion criteria: history of medicinal allergy; history of cardiac block and dyserythia; use of drugs such as calcium-blocker adrenergic receptor antagonist-angiotensin inhibitors; gestational age less than 36 weeks; hypertension and preeclampsia; gestational diabetes; coagulopathy uterus; anesthesia site infection; high intracranial pressure and BMI greater than 35.

Intervention groups

In the intervention group, intrathecal injection of 3 µg dexmedetomidine with 12.5 mg bupivacaine is used. In the control group, intrathecal injection of 25 micrograms of fentanyl plus 12.5 mg of bupivacaine is used.

Main outcome variables

Postoperative Pain Using NRS Scale; Time of First Dose of Postoperative Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191021045175N1**
Registration date: **2019-12-11, 1398/09/20**
Registration timing: **prospective**

Last update: **2019-12-11, 1398/09/20**
Update count: **0**

Registration date

2019-12-11, 1398/09/20

Registrant information

Name

Seyed hosein Khademi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 2738

Email address

khademihs@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The comparison of Addition of Dexmedetomidine and Fentanyl in Spinal Anesthesia with Bupivacaine in Cesarean Section

Public title
The Effect of dexmedetomidine on pain control of post cesarean section

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
ASA I, II Age: 18 to 45 years old Candidate for elective cesarean section

Exclusion criteria:
History of medicinal allergies History of cardiac block and dysrythmia Use of drugs such as calcium blocker-adrenergic receptor antagonist-angiotensin inhibitors Gestational age less than 36 weeks Hypertension and preeclampsia Gestational diabetes Coagulopathy Intrauterine growth restriction Anesthesia infection High intracranial pressure BMI greater than 35

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients will be enrolled in the study according to available sampling and then divided into two groups by simple random method via computer.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The study subjects, evaluators and analyzor will be blinded for the intervention and control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad Medical School

Street address
Shariati Square. University Ave. Imam Reza Hospital

City
mashhad

Province
Razavi Khorasan

Postal code
1234567890

Approval date
2019-10-13, 1398/07/21

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.528

Health conditions studied

1

Description of health condition studied
Duration of analgesia after spinal anesthesia

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Duration of analgesia after spinal anesthesia

Timepoint
Postoperatively in recovery time up to 2 hours and then in every two hours up to 8 hours and then every 4 hours up to 24 hours after surgery

Method of measurement
Numerical Rating Scale (NRS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, intrathecal injection of 3 µg dexmedetomidine with 12.5 mg bupivacaine was used.

Category
Treatment - Drugs

2

Description
In the control group, intrathecal injection of 25 micrograms of fentanyl plus 12.5 mg of bupivacaine is

used.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Maternity ward of Imam Reza hospital in Mashhad

Full name of responsible person
Seyed Hosein Khademi

Street address
Shariati Square. Imam Reza Hospital. Building 610. Office of Anesthesiology

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9137913316

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khademihs@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person
Dr Mohsen Tafaghodi

Street address
khorasan razavi - mashhad - university street - in front of university street 18 - Vice chancellor for research, Mashhad University of Medical Sciences

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tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Private

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
Mashhad University of Medical Sciences

Full name of responsible person
Seyed Hosein Khademi

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

Contact

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seyed hosein khademi

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Latest degree
Subspecialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
DATA IS PRIVATE

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
No - There is not 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
Comparison of the efficacy of adding dexmedetomidine and fentanyl in spinal anesthesia with bupivacaine in cesarean sectio

When the data will become available and for how long
20/09/2020

To whom data/document is available
ALL

Under which criteria data/document could be used
For method and results distribution

From where data/document is obtainable
Mashhad University of Medical Sciences

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

Comments