Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative Study of Fentanyl vs Dexmedetomidine as Adjuvants to Intrathecal Bupivacaine on post oprative pain in Cesarean Section

Protocol summary

Study aim
The effect of fentanyl and dexmedetomidine as adjuvants on pain after cesarean section

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 is performed on 100 patients. Patients are randomly divided into two groups (by lottery method).

Settings and conduct
The location of this study is Valiasr hospital in Birjand city in 1401-1400. The severity of patients' pain will be evaluated according to VAS scoring by the intern. Intern and patients are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: informed consent, ASA class 1 and 2, term pregnancy, non-emergency cesarean section. Exclusion criteria: drug addiction, dissatisfaction with spinal anesthesia, duration of surgery more than 1 hour, pregnancy with ASA 3 and above; patients with brain trauma, patients with spinal deformity; Inability to position the patient, spinal infection, hypersensitivity to local anesthetic drugs, high ICP and the presence of coagulation disorders and heart valve problems (especially AS).

Intervention groups
Patients in the control group under spinal anesthesia with marcaine 0.5% 2 cc (10 mg) + fentanyl 0.5 cc (25 micrograms) total 2.5 cc, and the intervention group marcaine 5% (10 mg) + dex duodenum diluted cc / 5 0 (5 micrograms) will be a total of 2.5 cc. The needle used is a Quinke gauge needle 25 gauge and the speed of drug injection in spinal anesthesia will be 0.2 cc / sec and anesthesia will be performed in a sitting position in L4 and L3. Patients' surgery will be performed by a surgeon. Patients' pain at intervals of 1, 2, 3, 4, 8 and 12 hours will be assessed by the audiologist using the visual-auditory assessment (VAS). Also, the time of the first request for analgesic drug by the patient.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211012052747N1**
Registration date: **2021-11-24, 1400/09/03**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-24, 1400/09/03**
Update count: **0**

Registration date
2021-11-24, 1400/09/03

Registrant information

Name
nadere mohammadshahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 56 3272 7626

Email address
naderemohammadshahi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-14, 1400/08/23

Expected recruitment end date
2022-05-13, 1401/02/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparative Study of Fentanyl vs Dexmedetomidine as Adjuvants to Intrathecal Bupivacaine on post oprative pain in Cesarean Section

Public title
The effect of fentanyl and dexmedetomidine as adjuvants on pain after cesarean section

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having informed consent to enter the study ASA Class 1 and 2 Term pregnancy Singleton Non-emergency cesarean section

Exclusion criteria:
Drug addiction Dissatisfaction with spinal anesthesia Duration of surgery more than 1 hour Pregnancy with ASA 3 and above Patients with head trauma Patients with spinal deformity Inability to position the patient Infection in site of spinal anesthesia Hypersensitivity to local anesthetic drugs High ICP Coagulation disorders and heart valve problems (especially AS)

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients are randomly divided into two groups in such a way that each patient who met the inclusion criteria before going to the operating room will be randomly drawn (color cards) in one of the two groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The intern determines the intensity of pain in patients without being aware of the patients' group. Patients and the evaluator do not know about their group, and the medication received (double-blind study).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Birjand University of Medical Sciences

Street address
Ghafari blvd,Birjand town

City
Birjand

Province
South Khorasan

Postal code
۹۷۱۷۸۵۳۵۷۷

Approval date
2021-11-14, 1400/08/23

Ethics committee reference number
IR.BUMS.REC.1400.249

Health conditions studied

1

Description of health condition studied
Evaluation of pain in patients after cesarean section with spinal anesthesia by marcaine and dexmedetomidine

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Determine the average pain score

Timepoint
Immediately after regaining consciousness and 1, 2, 3, 4, 8 and 12 hours after surgery

Method of measurement
Using visual-auditory assessment (VAS) criteria by the study leader

Secondary outcomes

1

Description
Blood pressure

Timepoint
immediately after recovery and 1, 2, 3, 4, 8 and 12 hours after surgery

Method of measurement
Sphygmomanometer

2

Description
Pulse beats

Timepoint

immediately after recovery and 1, 2, 3, 4, 8 and 12 hours after surgery

Method of measurement

Physical examination. patients' pulse is counted in one minute.

Intervention groups

1

Description

Intervention group: Patients undergoing spinal anesthesia with marcaine 5% (10 mg) + dex duodenomidine diluted 0.5 cc (5 micrograms) will be 2.5 cc in total. The needle used is a Quinke gauge needle 25 gauge and the speed of drug injection in spinal anesthesia will be 0.2 cc / sec and anesthesia will be performed in a sitting position in L4 and L3. Patients' surgery will be performed by a surgeon. Patients' pain at intervals of 1, 2, 3, 4, 8 and 12 hours will be assessed by the audiologist using the visual-auditory assessment (VAS). Also, the time of the first request for analgesic drug by the patient and the dose of the received drug are recorded and in case of VAS> 4 - pethidine 0.5 mg / kg will be injected. Marcaine from Aspen company is 5 mg / ml. Dex Medomidine is from Elixir Boroujerd Company.

Category

Treatment - Drugs

2

Description

Control group: Patients under spinal anesthesia with marcaine 0.5% 2 cc (10 mg) + fentanyl 0.5 cc (25 micrograms) will be placed in total 2.5 cc. The needle used is a Quinke gauge needle 25 gauge and the speed of drug injection in spinal anesthesia will be 0.2 cc / sec and anesthesia will be performed in a sitting position in L4 and L3. Patients' surgery will be performed by a surgeon. Patients' pain at intervals of 1, 2, 3, 4, 8 and 12 hours will be assessed by the audiologist using the visual-auditory assessment (VAS). Also, the time of the first request for analgesic drug by the patient and the dose of the received drug are recorded and in case of VAS> 4 - pethidine 0.5 mg / kg will be injected. Marcaine from Aspen company is 5 mg / ml. Fentanyl is from Darupakhsh Tehran Iran Company and 10 cc vials in 50 micrograms.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Bibi Fateme Shakhs Imampoor

Street address

Ghafari Blvd, Birjand,South Khorasan Province,

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97179 64151

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valiasr@bums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Tooba Kazemi

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public_r@bums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Bibi fateme Shakhs Imampoor

Position

Specialist and assitanat professor

Latest degree

Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
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Position
Assistant Professor
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Specialist
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Person responsible for updating data

Contact
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Position
Intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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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 related to hemodynamic parameters of the subjects included in the study, including pain, heart rate. Patients' systolic and diastolic blood pressure are measured at regular intervals after the person has been identified and the effect of the interventions is described in a general article.
When the data will become available and for how long
Accessibility after publishing the article
To whom data/document is available
Published data is accessible to all people working in different fields.
Under which criteria data/document could be used
In all circumstances
From where data/document is obtainable
After completing the study, the documents will be registered in the Pazhoohan.
What processes are involved for a request to access data/document
After sending the request
Comments