Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the effect of adding Dexamethasone and Fentanyl to Bupivacaine in transverse abdominal plane block (TAP) on pain intensity after cesarean section by spinal anesthesia in Sari Emam hospital in 1401

Protocol summary

Study aim

Comparison of the effect of adding dexamethasone and fentanyl to bupivacaine in transverse abdominal plane (TAP) block on pain intensity after cesarean section using spinal anesthesia.

Design

Clinical trial with a control group, with parallelgroups,3blindstrains,randomized, phase 2 on 60 patients. Now, randomization will be done by block method (Randomization Block). This process will be done with Random allocation software. Data entry and analysis will be done in SPSS version 25 software.

Settings and conduct

The current study is a three-blind randomized clinical trial that will be conducted at Imam Khomeini Educational-Therapeutic Hospital in Sari in Mazandaran province on women who are candidates for elective cesarean birth between 18 and 50 years old. These women are selected for the study based on American Society of Anesthesiology (ASA) physical status I and Ⅱ.

Participants/Inclusion and exclusion criteria

Patients 18-50 years old, patients undergoing cesarean section under spinal anesthesia, patients with anesthesia class I and II of the American Society of Anesthesiology (ASA) (ASA definition I = healthy patient without organic disease, (VAS; scale 0-10), They were eligible to provide written informed consent to enroll in the study. Body mass index = 23.9-18.5 kg/m2, absence of coagulopathy, absence of alcohol or drug addiction, exclusion criteria, presence of chronic pain, or havingunderlyingdiseasestakingpainkillersbeforesurgery, presenceofinfectionhistoryof abdominal surgery or trauma, respiratory tract infection within 2 weeks

Intervention groups

Group (1) 50 micrograms of fentanyl plus 17 ml of 0.25%bupivacaineand2mlof 0.9% normal saline in a total volume of 20 ml on each side Group (2) 4 mg of dexamethasone plus17mlof0.25%bupivacaineand2mlof0.9% normal saline in a total volume of 20 ml on each side

Main outcome variables

Pain intensity, nausea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161126031095N3**
Registration date: **2023-06-21, 1402/03/31**
Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**
Update count: **0**

Registration date

2023-06-21, 1402/03/31

Registrant information

Name

Alieh Zamani Kiasari

Name of organization / entity

Mazandaran University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of adding Dexamethasone and Fentanyl to Bupivacaine in transverse abdominal plane block (TAP) on pain intensity after cesarean section by spinal anesthesia in Sari Emam hospital in 1401

Public title

Comparison of the effect of adding Dexamethasone and Fentanyl to Bupivacaine in transverse abdominal plane block (TAP) on pain intensity after cesarean section by spinal anesthesia in Sari Emam hospital in 1401

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 18-50 years old Patients undergoing cesarean section under spinal anesthesia Patients with American Society of Anesthesiology (ASA) class I and II anesthesia status (ASA definition = healthy patient without organic, biochemical or mental disease and ASAII = patient with mild systemic disease such as mild asthma - controlled hypertension - disease has no effect on activity not daily - the possibility of affecting anesthesia and surgery) Patients who can perceive and evaluate their pain on a visual analog pain scale. (VAS; scale 0-10) They were eligible to provide written informed consent to enroll in the study Body mass index kg/m2 = 23.9-18.5 Absence of coagulopathy No alcohol or drug addiction

Exclusion criteria:

Having chronic pain, or having underlying diseases such as moderate or severe heart, kidney, lung or nerve diseases, significant scoliosis or kyphosis, excessive obesity Taking painkillers before surgery Infection at the injection site History of abdominal surgery or trauma Respiratory tract infection within 2 weeks New York Heart Association Class >II cardiac status and psychiatric disorders that interfere with pain perception and evaluation They had a history of anaphylaxis using bupivacaine Patients who did not tolerate spinal anesthesia well and had to be converted to general anesthesia for cesarean section Individuals who could not provide informed consent or patients who did not wish to participate in the study

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

There are different methods for random allocation in clinical trial studies, which is one of these methods, and in cases such as when the number in each group is to be selected in equal proportion, this method is appropriate. The size of each block is usually determined as a multiple of 4 or six or eight and so on. The size of all blocks can be considered as a fixed number or it can be considered variable based on the mentioned multiples. After selecting the eligible samples, in this study, randomization will be done by Block Randomization method. became. This process will be done with random allocation software. With the mentioned software, 10 blocks of six will be created. Samples will be assigned to each group based on randomly generated numbers.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Before starting the study, the list of people will be randomly assigned to 2 study groups using a computer. Based on this list, envelopes are prepared, inside which the name of one of the treatment groups is written based on the list of random numbers. These envelopes will be provided to the first expert, and if the patients meet the entry criteria, an envelope will be opened for each patient and their treatment group will be determined based on it. The drug is prepared for injection by the mentioned expert and is handed over to the second expert (who does not know the type of drug) and finally the drug is given to the anesthesia assistant performing TAP Block. The completer of the checklist also has no knowledge of the drug group assigned to each patient.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Imam Khomeini Hospital of Sari - Mazandaran University of Medical Sciences

Street address

Office Building Ethics Committee of Imam Khomeini Hospital Amir Mazandarani Blvd.

City

Sari

Province

Mazandaran

Postal code

48166-33131

Approval date

2023-03-13, 1401/12/22

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1402.010

Health conditions studied

1

Description of health condition studied

Other acute postprocedural pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Postpartum pain intensity

Timepoint

0/2/4/6/12 and 24/hours after the operation

Method of measurement

Visual Analogue Scale

2

Description

Sedation

Timepoint

0/2/4/6/12 and 24/hours after the operation

Method of measurement

Sedation criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 50 micrograms of fentanyl plus 17 ml of 0.25% bupivacaine and 2 ml of 0.9% normal saline in a total volume of 20 ml on each side

Category

Treatment - Drugs

2

Description

Intervention group: 4 mg of dexamethasone plus 17 ml of 0.25% bupivacaine and 2 ml of 0.9% normal saline in a total volume of 20 ml on each side

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Sari

Full name of responsible person

Alieh Zamani Kiasari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Alieh Zamani Kiasari

Position

Assistance professor of Anesthesiology and Intensive Care

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate Professor of Anesthesiology and Vegetative Care

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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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

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