Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Comparing the preventive effect of infiltration into the surgical incision "bupivacaine" with "bupivacaine plus dexmedetomidine" in reducing pain after caesarean section.

Protocol summary

Study aim
Determining and comparing the preventive effect of infiltration into the surgical incision "bupivacaine" with "bupivacaine plus dexmedetomidine" in reducing pain after caesarean section.

Design
A randomized, double-blinding clinical trial, with parallel groups, Phase 2 on 80 patients

Settings and conduct
In this randomized double-blind clinical trial study, 80 eligible patients referred to Beheshti and Al-Zahra Hospital in Isfahan will be included in the study and will be randomly divided into two groups. In the first and second groups, respectively, "bupivacaine" and "bupivacaine plus dexmedetomidine" were prescribed as local subcutaneous wound infiltration. Then the pain intensity, hemodynamic parameters, and complications of the patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria
The inclusion criteria of the study include patients who are candidates for cesarean surgery of the elective type, the maximum duration of the operation is 90 minutes, the cesarean surgery is performed under spinal anesthesia or anesthesia from the back, and consent to participate in the study. Exclusion criteria include having an uncontrollable underlying disease, twin pregnancy and higher, having a history of allergies to the drugs used and the lack of opioids' effect on them, and having acute or chronic pain before surgery.

Intervention groups
First intervention group: In this group, local subcutaneous wound infiltration of 0.25% bupivacaine (3 mg/kg) diluted with normal saline up to 40 ml will be done. Second intervention group: In this group, local subcutaneous wound infiltration of 0.25% bupivacaine (3 mg/kg) plus dexmedetomidine (1.5 µg/kg) of body weight diluted with normal saline up to 40 ml will be done.

Main outcome variables
Pain; Blood pressure; Percentage of oxygen saturation (SPO2); Heart rate; Complications

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N60**
Registration date: **2022-09-12, 1401/06/21**
Registration timing: **prospective**

Last update: **2022-09-12, 1401/06/21**
Update count: **0**

Registration date
2022-09-12, 1401/06/21

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

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asimaghami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-22, 1401/06/31

Expected recruitment end date
2023-04-20, 1402/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the preventive effect of infiltration into the surgical incision "bupivacaine" with "bupivacaine plus dexmedetomidine" in reducing pain after caesarean section.

Public title

Comparing the effect of "bupivacaine" with "bupivacaine plus dexmedetomidine" in reducing pain after caesarean section.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for caesarean section (for the first time) Elective caesarean section The maximum duration of operation is 90 minutes Performing caesarean section surgery using spinal anesthesia or anesthesia from the back Consent to participate in the study

Exclusion criteria:

Uncontrollable underlying disease (ASA3 and higher) Twin pregnancy and above[3] Having a history of allergies to the drugs used (such as bupivacaine, dexmedetomidine) The lack of effect of opioids on them and having acute or chronic pain before surgery

Age

No age limit

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: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 80 eligible patients are randomly selected. Then the letters A and B are written on 400 sheets and each one is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to achieve the double-blind study, two drugs, bupivacaine and the combination of bupivacaine and dexmedetomidine, will be prepared and placed in the bag daily before surgery (without the knowledge of the researcher) and will be labeled A, B. And is given daily to the anesthesiologist (researcher). Therefore, the patient, care provider, investigator, outcome assessor, and data analyzer will not be aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfehan

Postal code

8179964167

Approval date

2022-06-22, 1401/04/01

Ethics committee reference number

IR.MUI.MED.REC.1401.131

Health conditions studied

1

Description of health condition studied

Cesarean delivery

ICD-10 code

O82

ICD-10 code description

Encounter for cesarean delivery without indication

Primary outcomes

1

Description

Pain

Timepoint

Immediately after entering the recovery and every half hour to the first two hours and every hour to the second hour after surgery

Method of measurement

Visual analog scale (VAS)

2

Description
Blood presure
Timepoint
Upon entering the study and every half hour to two hours and every hour to two hours after surgery
Method of measurement
Monitoring device

3

Description
Heart rate
Timepoint
Upon entering the study and every half hour to two hours and every hour to two hours after surgery
Method of measurement
Monitoring device

4

Description
Oxygen saturation percentage (SPO2)
Timepoint
Upon entering the study and every half hour to two hours and every hour to two hours after surgery
Method of measurement
Monitoring device

Secondary outcomes

1

Description
Nausea
Timepoint
After surgery
Method of measurement
Observational

2

Description
Vomiting
Timepoint
After surgery
Method of measurement
Observational

3

Description
Chills
Timepoint
After surgery
Method of measurement
Observational

Intervention groups

1

Description
First intervention group: In this group, local subcutaneous wound infiltration of 0.25% bupivacaine (3 mg/kg) diluted with normal saline up to 40 ml will be done.
Category
Treatment - Drugs

2

Description
Second intervention group: In this group, local subcutaneous wound infiltration of 0.25% bupivacaine (3 mg/kg) plus dexmedetomidine (1.5 µg/kg) of body weight diluted with normal saline up to 40 ml will be done.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Alireza Hoghooghi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
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Full name of responsible person
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Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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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
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available