Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of intravenous Dexamethasone injection with Intrathecal injection On Pain and Nausea and Vomiting of patients undergoing Caesarean section by Spinal anesthesia with Sufentanil; a double-blind randomized clinical trial

Protocol summary

Study aim
Comparison of the effect of intravenous and intrathecal dexamethasone injection on pain and nausea and vomiting in patients undergoing cesarean section.

Design
Double-Blind Randomized Clinical Trial, Phase 3 on 90 patients, Web-based randomization software was used for randomization.

Settings and conduct
The present study will be conducted in the field of reducing pain and nausea and vomiting in 90 patients aged 20-40 who are candidates for caesarean section by spinal anesthesia in Bent Al Hodi Hospital. Patients are divided into three groups in a blocked random allocation using the web-based system. Evaluation of the intensity of pain, nausea and vomiting of patients using the VAS tool during recovery, 30 minutes after the operation, then every 30 minutes, then 6 hours, 12 hours , 24 hours after the operation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The patient should be alert, should be a candidate for cesarean surgery with spinal anesthesia, Patient should not have the Absolute contraindications for spinal anesthesia. Exclusion criteria: Dissatisfaction of patients during intervention, the requirement of general anesthesia after spinal anesthesia for the patient.

Intervention groups
In the first group(A): Patients in combination with the main drug (Bupivacaine); They will receive Sufentanil 25 micrograms and 8mg Dexamethasone Intrathecal (2cc). In the second group(B): Patients in combination with the main drug (Bupivacaine); 25 micrograms Sufentanil and immediately after doing spinal; All patients will receive 8mg of dexamethasone (2cc) intravenously. In the third group(C): patients in combination with the main drug (bupivacaine); Sufentanil 25 micrograms and 2cc of intrathecal distilled water will be given. Also, immediately after doing the spinal; All patients will receive 2cc of distilled water intravenously.

Main outcome variables
Pain, nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141001019359N16**
Registration date: **2022-11-21, 1401/08/30**
Registration timing: **prospective**

Last update: **2022-11-21, 1401/08/30**
Update count: **0**

Registration date
2022-11-21, 1401/08/30

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-20, 1401/09/29

Expected recruitment end date
2023-03-20, 1401/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of intravenous Dexamethasone injection with Intrathecal injection On Pain and Nausea and Vomiting of patients undergoing Caesarean section by Spinal anesthesia with Sufentanil; a double-blind randomized clinical trial

Public title
Comparison of the effect of intravenous Dexamethasone injection with Intrathecal injection On Pain and Nausea and Vomiting of patients undergoing Caesarean section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patient should not have the Absolute contraindications for spinal anesthesia. The patient should not have a history of previous surgery. The patient should not have mental and psychological problems and peripheral and central neuropathy. The patient should not have cardiovascular problems. ASA I & II Patients must be vigilant
Exclusion criteria:
Patients who are addictive or have drug abuse. Patient who has a history of taking beta blockers and Alpha 2-agonists and Calcium Channel Blockers. For any reason, If we have to perform General Anesthesia after Spinal Anesthesia
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling in this study will be that first in order to enter the study patients will be in the form of non-random sampling of the type "available" and then divide them into three groups by randomly assigned blocking using a web-based system. Random blocking at www.randomization.com will be done in 15 blocks of 6. So that in each block, there are 2 people in the first group (A), two people in the second group (B) and two people in the third group (C). After a random sequence was identified in all blocks, cards were written by writing C, B, and A to indicate which group each patient was assigned to, and by someone other than the research team from 1 to 90 in all blocks, respectively. They are numbered and these cards are placed in sealed non-transparent envelopes, respectively. Then, in order to hide the random allocation, when the patient visits, the opaque sealed envelope will be opened and then one by one, it will be determined for each sample of the relevant group.
Blinding (investigator's opinion)
Double blinded
Blinding description
None of the participants in the study will be aware of the randomization list, and in order to conceal the randomization process, the groups will be placed in closed envelopes in the reception area and will be assigned to the eligible individuals who enter the study. Also, to blind the patients to the study groups, all patients will receive all the interventions of the same groups with placebo. in order to make the study double-blind, the data will be measured and recorded by a person who is unaware of the groupings. Also, the preparation of drugs in each group is done by an anesthesiologist, and another anesthesiologist will perform the spinal block, who is unaware of the drugs in each syringe.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of North Khorasan University of Medical Sciences
Street address
Vice Chancellor for Research of North Khorasan University of Medical Sciences, Bojnurd
City
Bojnurd
Province
North Khorasan
Postal code
9416678894
Approval date
2022-10-20, 1401/07/28
Ethics committee reference number
IR.NKUMS.REC.1401.061

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
R52.9
ICD-10 code description
Pain, unspecified

2

Description of health condition studied
Nausea and Vomiting
ICD-10 code
R11.2
ICD-10 code description
Nausea with vomiting, unspecified

Primary outcomes

1

Description
Pain after surgery
Timepoint
During recovery, 30 minutes after surgery and then every 30 minutes until the 2th hour, then at 6, 12 and 24 hours after surgery.
Method of measurement
Visual Analog Score (VAS)

2

Description
Nausea and Vomiting
Timepoint
During recovery, 30 minutes after surgery and then every 30 minutes until the 2th hour, then at 6, 12 and 24 hours after surgery.
Method of measurement
Scale for measuring nausea and vomiting

Secondary outcomes

1

Description
level of analgesia
Timepoint
After spinal procedure
Method of measurement
Pin Prink Index

2

Description
Duration of analgesia
Timepoint
After the patient leaves the operation room
Method of measurement
Clock

3

Description
Hemodynamic parameters
Timepoint
After performing the spinal technique, in the first 15 minutes every 5 minutes and then every 15 minutes until the end of the surgery
Method of measurement
Using the monitoring device

4

Description
Medication side effects
Timepoint
From the end of surgery to 24 hours after
Method of measurement
Researcher-made questionnaire

Intervention groups

1

Description
Intervention group 1: In combination with the main drug (bupivacaine); patients will receive 25 microgram Sufentanyl and 8 mg Dexamethasone Intrathecally (2cc). Also, immediately after doing the spinal; All patients will receive 2cc of Distilled water intravenously.
Category
Prevention

2

Description
Intervention group 2:In combination with the main drug (bupivacaine); patients will receive 25 microgram Sufentanyl and 2cc of Distilled water Intrathecally. Also, immediately after doing the spinal; All patients will receive 8 mg of dexamethasone (2cc) intravenously.
Category
Prevention

3

Description
Control group: In combination with the main drug (bupivacaine); patients will receive 25 microgram Sufentanyl and 2cc of Distilled water Intrathecally. Also, immediately after doing the spinal; All patients will receive 2cc of Distilled water intravenously.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Bint Al-Houdi Hospital
Full name of responsible person
Dr Zohre Roohande
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Sponsors / Funding sources

1

Sponsor
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iran6289@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bojnourd 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
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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