# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

11 Jun 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**

**Name**
Hossein Zeraati

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 58 3151 0000

**Email address**
zeraatih911@mums.ac.ir

**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
**Street address**
Honar St, Zaishgah Crossroad, Western Taleghani St, Bojnord, North Khorasan Province
**City**
Bojnurd
**Province**
North Khorasan
**Postal code**
7487794149
**Phone**
+98 58 3223 6551
**Email**
zeraatih@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Bojnourd University of Medical Sciences
**Full name of responsible person**
Amirali Ghahramani
**Street address**
Vice Chancellor for Research, Shariati Ave, North Khorasan University of Medical Sciences, Bojnurd, Iran
**City**
Bojnurd
**Province**
North Khorasan
**Postal code**
9416678894
**Phone**
+98 58 3151 1421
**Email**
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**
**Name of organization / entity**
Bojnourd University of Medical Sciences
**Full name of responsible person**
Ali Esmaeili
**Position**
Faculty Anesthesiologist
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
**Street address**
North Khorasan School of Medicine, Bojnurd, iran
**City**
Bojnurd
**Province**
North Khorasan
**Postal code**
9416678894
**Phone**
0098583151
**Email**
dresmaely8@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Bojnourd University of Medical Sciences
**Full name of responsible person**
Ali Esmaeili
**Position**
Faculty Anesthesiologist
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
**Street address**
North Khorasan School of Medicine, Bojnurd, iran
**City**
Bojnurd
**Province**
North Khorasan
**Postal code**
9416678894
**Phone**
0098583151
**Fax**
**Email**
dresmaely8@gmail.com
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Bojnourd University of Medical Sciences
**Full name of responsible person**
Ali Esmaeili

**Position**
Faculty Anesthesiologist
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
**Street address**
North Khorasan School of Medicine, Bojnurd, iran
**City**
Bojnurd
**Province**
North Khorasan
**Postal code**
9416678894
**Phone**
0098583151
**Fax**
**Email**
dresmaely8@gmail.com
**Web page address**

## 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