Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparing the effect of combined intrathecal dexamethasone-bupivacaine with bupivacaine alone for spinal anesthesia in a cesarean section

Protocol summary

Study aim

Comparing the efficacy of intrathecal bupivacaine alone with a combination of bupivacaine and dexamethasone on the duration of spinal analgesia.

Design

A randomized, double-blind clinical trial with a parallel groups design; phase 3; on 50 patients; divided into two groups of intervention and control by random software allocation.

Settings and conduct

This study will be conducted in Urmia Kosar hospital. This study will include 50 women randomly allocated into two groups: the intervention and the control group. The patients and the nurse who will take care of them during the procedure will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 21 and 40 years, elective cesarean section, having stable vital signs, having second to fifth childbirth. Exclusion criteria: having a stillbirth history, the presence of a clear anomaly in the fetus, pregnancy complications, depression, or proven mental disorder.

Intervention groups

The control group received 12 mg of 0.5% hyperbaric bupivacaine diluted in preservative-free normal saline (2 ml), and patients of the intervention group received 12 mg of 0.5% hyperbaric bupivacaine and 8 mg preservative-free dexamethasone with the Dexadic brand name (2 ml), overall 5 ml volume intrathecally.

Main outcome variables

Duration of analgesia; sensory block after a cesarean; the time needed to reach T10, and T4 anesthesia; time required for the return of anesthesia to T10; duration of motor block after cesarean section; time required to reach the maximum movement block; anesthesia complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221126056613N2**
Registration date: **2023-03-27, 1402/01/07**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-27, 1402/01/07**
Update count: **0**

Registration date

2023-03-27, 1402/01/07

Registrant information

Name

aliakbar nasiri

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

2023-03-04, 1401/12/13

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effect of combined intrathecal dexamethasone-bupivacaine with bupivacaine alone for spinal anesthesia in a cesarean section

Public title
Comparing the effect of combined intrathecal dexamethasone-bupivacaine with bupivacaine

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
21-40 aged pregnant women candidate for elective cesarean section Patients with ASA I and ASA II Cesarean section by spinal anesthesia Satisfaction to participate in the project Patients with stable vital signs Women with second to fifth childbirth

Exclusion criteria:
Women with stillbirth history The presence of a clear anomaly in the fetus Pregnancy complications (previa, accreta, preeclampsia, placental abruption, etc.) Depression or proven mental disorder in pregnant women

Age
From **21 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients, using random allocation software, were randomly divided into median and paramedian groups. By selecting the simple randomization method in the randomization box and entering the determined total sample size in this software, numbers were given to the patients and the patients were allocated into two groups according to computer-generated numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients and the nurse who cares for participants during the trial will be blinded by the intervention and control groups. Written consent is obtained from patients, but at the same time, patients do not know whether they are in the placebo or intervention group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences

Street address
Urmia University of Medical Sciences; Resalat street; Jahad Blvd; Urmia; Iran.

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2023-03-04, 1401/12/13

Ethics committee reference number
IR.UMSU.REC.1397.483

Health conditions studied

1

Description of health condition studied
Duration of spinal analgesia

ICD-10 code
O74.8

ICD-10 code description
Other complications of anaesthesia during labour and delivery

Primary outcomes

1

Description
The sensory level of the block

Timepoint
Measuring the patient's sensory block level at intervals of 1 minute to 20 minutes and then during and after surgery at intervals of 10 minutes until reaching T10.

Method of measurement
It was examined bilaterally with the tip of the spinal needle along the midaxillary line.

2

Description
The motor level of the block

Timepoint
Measuring the patient's motor block level at intervals of 1 minute to 20 minutes and then during and after surgery at intervals of 10 minutes until reaching T10.

Method of measurement
The motor block was assessed using the Modified Bromage scale.

3

Description
pain assessment
Timepoint
After the sensory level returned to T10, every 30 minutes, the patient's pain sensation in the surgical site, abdomen and pelvis will be evaluated with the help of VAS score until the time of reaching 6 ≥ VAS score will be recorded.
Method of measurement
Visual analog pain scale (VAS)

4

Description
side effecs of anesthesia
Timepoint
The side effects of anesthesia will be measured after surgery for one week (the first two days every 8 hours and until the end of the week once a day).
Method of measurement
By visual sign

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Spinal anesthesia was performed in the sitting position at L4 -L5 level through a midline approach using a 25-gauge Quincke spinal needle. The patients of the intervention group received 12 mg of 0.5% hyperbaric bupivacaine and 8 mg preservative-free dexamethasone with the Dexadic brand name (2 ml), overall 5 ml volume intrathecally. The drug was made available to the researchers of this project by Caspin Pharmaceutical Company.
Category
Prevention

2

Description
Control group: Spinal anesthesia was performed in the sitting position at L4 -L5 level through a midline approach using a 25-gauge Quincke spinal needle. The control group received 12 mg of 0.5% hyperbaric bupivacaine diluted in preservative-free normal saline (2 ml) with the same appearance as dexamethasone. The drug was made available to the researchers of this project by Caspin Pharmaceutical Company.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Kosar Hospital
Full name of responsible person
Dr. Aliakbar Nasiri
Street address
Hasani Street, Kosar Hospital, Urmia, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Dr. Aliakbar Nasiri

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable