

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Oct 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

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

nasiriali7@gmail.com

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; Jihad 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 $6 \geq$ VAS score will be recorded.

Method of measurement

Visual analog pain scale (VAS)

4

Description

side effects 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

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 915 341 6876

Email

nasiriali7@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saber Golizadeh

Street address

Resalat street, Jahad Blv., Urmia University of Medical Sciences, Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 915 341 6876

Email

nasiriali7@gmail.com

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

Street address

Ershad Street, Imam khomeini Hospital, Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 915 341 6876

Email

nasiriali7@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Ali Akbar Nasiri

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Ershad street, Imam Khomeini Hospital, Urmia Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 915 341 6876

Email

nasiriali7@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Aliakbar Nasiri

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam khomini university hospital-Eeshad AVE-
Modarres Blvd-urmia-iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3346 9931

Fax**Email**

nasiriali7@gmail.com

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