Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative study of the preventive effect of different doses of dexamethasone and paracetamol on postoperative pain in patients undergoing cesarean section

Protocol summary

Study aim
Comparison of the preventive effect of different doses of dexamethasone and intravenous paracetamol on the intensity of postoperative pain in patients undergoing cesarean section under spinal anesthesia

Design
This study was a phase III, randomized, controlled, parallel-group, triple-blind clinical trial. Randomization was performed using a sequence generator at Random.org.

Settings and conduct
Eligible patients provided written informed consent and entered the study. Baseline vital signs were recorded, intravenous metoclopramide was administered, warmed Ringer's lactate preloading was performed, followed by spinal anesthesia. Patients were randomly assigned to one of five groups; medications were prepared in identical coded syringes to maintain blinding. Postoperative pain intensity and possible adverse events were recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women aged 18–45 years with an American Society of Anesthesiologists (ASA) physical status I–II who are candidates for elective cesarean section under spinal anesthesia. Exclusion criteria: Presence of significant underlying medical diseases, alcohol or substance abuse, and any contraindication to spinal anesthesia.

Intervention groups
Patients are randomly assigned to five groups to receive either intravenous dexamethasone at doses of 2, 4, or 6 mg immediately after spinal anesthesia, intravenous paracetamol 1 g diluted in 100 mL of normal saline, or 100 mL of normal saline as the control. Postoperative pain intensity is assessed using the visual analog scale (VAS) for up to 8 hours after surgery, and the requirement for rescue analgesia and the occurrence of drug-related adverse effects are recorded.

Main outcome variables
Patients' pain intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240221061070N11**
Registration date: **2026-01-07, 1404/10/17**
Registration timing: **registered_while_recruiting**

Last update: **2026-01-07, 1404/10/17**
Update count: **0**

Registration date
2026-01-07, 1404/10/17

Registrant information

Name
Milad Masaeli

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
2025-11-22, 1404/09/01

Expected recruitment end date
2026-02-20, 1404/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the preventive effect of different doses of dexamethasone and paracetamol on postoperative pain in patients undergoing cesarean section

Public title
Preventive effect of dexamethasone and paracetamol on postoperative pain following cesarean section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Women with American Society of Anesthesiologists (ASA) physical status class I Age range between 18 and 45 years Candidates for elective cesarean section under spinal anesthesia
Exclusion criteria:
Known cardiac, pulmonary, hepatic, or renal disease Psychiatric disorders, diabetes mellitus, or thyroid dysfunction Body temperature at operating room admission < 36.5 °C or > 37.5 °C History of alcohol or substance abuse Use of vasodilator medications Requirement of intraoperative blood transfusion
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
After confirmation of the inclusion and exclusion criteria and obtaining written informed consent, eligible participants will be randomly allocated to one of the five study groups. Randomization will be performed using the Random Sequence Generator available at www.random.org. To ensure a balanced distribution of participants among the study groups, block randomization with fixed blocks of 15 will be applied, such that within each block participants are equally assigned to five groups (A, B, C, D, and E), including intravenous dexamethasone 2 mg, intravenous dexamethasone 4 mg, intravenous dexamethasone 6 mg, intravenous paracetamol 1 g, and normal saline (control group). Participant allocation will be carried out according to the order of enrollment and based on a pre-generated randomization list. Allocation concealment will be ensured by preparation of all study interventions in identical, coded syringes by an independent anesthesiologist who is not involved in patient assessment, and the prepared medications will be delivered to the study investigator. This study will be conducted as a triple-blind trial, in which the participants, the investigator, and the statistical analyst will remain unaware of the allocated treatment until completion of data analysis.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study is designed as a triple-blind randomized controlled trial to minimize bias during the intervention, outcome assessment, and data analysis phases. Participants will be blinded to both the allocated group and the type of medication administered. The medical staff directly involved in patient care during surgery and the postoperative period, including anesthesiologists and ward nurses, will also be unaware of group allocation. The outcome assessor, who records data related to pain assessment and patient satisfaction, will remain blinded to the type of intervention. Finally, the statistician responsible for the final data analysis will receive the dataset with coded group assignments and will be unaware of the treatment identities. To ensure blinding, all study medications will be prepared in identical, visually indistinguishable syringes and labeled with encrypted codes. The only unblinded individual will be an anesthesia assistant responsible for preparing and coding the syringes according to the randomization sequence; however, this individual will not participate in drug administration, patient assessment, or data analysis.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Al-Zahra Medical Research Centers, Isfahan University of Medical Sciences
Street address
Al-Zahra Research Centers Complex, Al-Zahra Hospital, Soffeh Street, Isfahan, Isfahan Province, Iran
City
Isfahan
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Isfehan
Postal code

8174675731

Approval date

2025-10-25, 1404/08/03

Ethics committee reference number

IR.ARI.MUI.REC.1404.197

Health conditions studied

1

Description of health condition studied

Post-Cesarean Pain (Postoperative Pain after Cesarean Section)

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Postoperative pain intensity after cesarean section

Timepoint

Postoperative pain intensity using the Visual Analog Scale (VAS) will be assessed at baseline (before administration of the study intervention and prior to the start of surgery) and subsequently at 2, 4, 6, and 8 hours after surgery (following receipt of the intervention).

Method of measurement

The primary variable (postoperative pain intensity) will be measured using the Visual Analogue Scale for pain assessment. This scale consists of a 10-centimeter horizontal line with “no pain” marked at one end (score 0) and “the worst pain imaginable” at the other end (score 10).At each predefined postoperative time point (0, 2, 4, 6, and 8 hours after the cesarean section), the patient will indicate the intensity of pain by marking a point on the line corresponding to their perceived pain level. The score is obtained by measuring the distance in centimeters from the “no pain” anchor to the patient’s mark.Before surgery, all participants will be instructed on how to use the scale to ensure a consistent and valid understanding of pain rating across subjects.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1 (Intravenous dexamethasone 2 mg):In this group, aiming to evaluate the preventive effect of low-dose dexamethasone on postoperative pain intensity, after obtaining written informed consent, patients will receive 10 mg of intravenous metoclopramide as premedication upon arrival in the operating room. Two 18-gauge intravenous catheters will then be inserted into the upper extremities, followed by preload hydration with warmed Ringer’s lactate solution (using a fixed fluid warmer for one hour, without the use of an in-line warming device) at a dose of 10 mL/kg over 30 minutes.Spinal anesthesia will be performed at the L4–L5 intervertebral space in the sitting position, using a 26-gauge Quincke spinal needle via the paramedian approach. All patients will receive 2.5 mL of 0.5% hyperbaric bupivacaine administered intrathecally.Immediately after completion of spinal anesthesia, the intervention drug consisting of 2 mg intravenous dexamethasone (manufactured by Iran Darou Pharmaceutical Company), diluted in a syringe containing normal saline (0.9%), will be administered slowly over approximately one minute via the intravenous route.To maintain blinding, all study medications will be prepared according to the randomization list by an anesthesiologist not involved in the execution of the study and will be provided to the study administrator in identical, coded syringes for administration.

Category

Prevention

2

Description

Intervention Group 2 (Intravenous dexamethasone 4 mg):In this group, aiming to evaluate the preventive effect of a moderate dose of dexamethasone on postoperative pain intensity, after obtaining informed consent, patients receive 10 mg of intravenous metoclopramide as premedication upon arrival in the operating room. Subsequently, two 18G intravenous catheters are inserted in the upper limbs, and preload with warmed Ringer’s lactate solution (10 mL/kg over 30 minutes) is performed.Spinal anesthesia is performed at the L4–L5 intervertebral space in the sitting position using a 26G Quincke needle via the paramedian approach, and 2.5 mL of 0.5% hyperbaric bupivacaine is injected.Immediately after spinal anesthesia, 4 mg of injectable dexamethasone sodium phosphate (a clear, colorless solution with a concentration of 4 mg/mL) is administered as a single intravenous dose, injected slowly over approximately one minute. The dexamethasone used is a commercially available product manufactured by Iran Darou Pharmaceutical Company.The medication is prepared by an anesthesiologist not involved in the research team, using identical syringes diluted with normal saline and coded to ensure complete blinding. Throughout the study, the drug is administered only once, with no repeated dosing.

Category

Prevention

3

Description

Intervention Group 3 (Intravenous dexamethasone 6 mg):In this group, aiming to evaluate the analgesic and anti-inflammatory effects of a high dose of dexamethasone, after obtaining informed consent, patients receive 10 mg of intravenous metoclopramide

as premedication upon arrival in the operating room. Subsequently, two 18G intravenous catheters are inserted in the upper limbs, and preload with warmed Ringer’s lactate solution at a dose of 10 mL/kg over 30 minutes is performed.Spinal anesthesia is carried out at the L4–L5 intervertebral space in the sitting position using a 26G Quincke needle via the paramedian approach, followed by injection of 2.5 mL of 0.5% hyperbaric bupivacaine.Immediately after spinal anesthesia, 6 mg of injectable dexamethasone sodium phosphate (a clear, colorless solution with a concentration of 4 mg/mL) is administered as a single intravenous dose, injected slowly over approximately one minute. The dexamethasone used is a commercially available preparation manufactured by Iran Darou Pharmaceutical Company.All study medications are prepared by an anesthesiologist not involved in the research team, using identical syringes diluted with normal saline and coded, in order to ensure complete triple blinding. The study drug is administered only once, with no repeated dosing during the trial.

Category

Prevention

4

Description

Intervention Group 4 (Intravenous paracetamol 1 g):In this group, aiming to evaluate the preventive effect of paracetamol on postoperative pain intensity following cesarean section, after obtaining informed consent, patients receive 10 mg of intravenous metoclopramide as premedication upon arrival in the operating room. Subsequently, two 18G intravenous catheters are inserted in the upper limbs, and preload with warmed Ringer’s lactate solution at a dose of 10 mL/kg over 30 minutes is performed.Spinal anesthesia is performed similarly to the other groups at the L4–L5 intervertebral space in the sitting position using a 26G Quincke needle via the paramedian approach, followed by injection of 2.5 mL of 0.5% hyperbaric bupivacaine.Then, 15 minutes before the start of cesarean surgery, 1 g of intravenous paracetamol (acetaminophen), provided as a ready-to-use injectable solution containing 10 mg/mL paracetamol, diluted in 100 mL of normal saline, is administered over 10–15 minutes using a microset infusion system. The paracetamol used is a commercially available product manufactured by Iran Darou Pharmaceutical Company.The study medication is prepared by an anesthesiologist not involved in the research team, using identical infusion sets and containers, diluted with normal saline and coded, to ensure complete blinding. The drug is administered only once during the study, with no repeated dosing.

Category

Prevention

5

Description

In the control group, after obtaining written informed consent, patients will receive 10 mg of intravenous metoclopramide as premedication upon arrival in the operating room. Two 18-gauge intravenous catheters will be inserted into the upper extremities, and preload hydration with warmed Ringer’s lactate solution will be administered at a dose of 10 mL/kg over 30 minutes.Spinal anesthesia, identical to that performed in the other groups, will be administered at the L4–L5 intervertebral space using a 26-gauge Quincke spinal needle via the paramedian approach, and 2.5 mL of 0.5% hyperbaric bupivacaine will be injected intrathecally.Following spinal anesthesia, patients in the control group will receive 100 mL of intravenous normal saline as a placebo, administered slowly over approximately one minute. This solution will be prepared in syringes identical in appearance to those used for the other study medications and coded in the same manner to maintain triple blinding.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Educational and Therapeutic Center

Full name of responsible person

Dr.Milad Masaeli

Street address

Apposite of Asman Hotel, The beginning of Shahid Motahari St., Felezzi Bridge, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholam Reza Asgari

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Research and Technology Vice-Chancellor, Building No. 4, Isfahan University of Medical Sciences and Health Services, Hazar Jarib St.

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Milad Masaeli

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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

The data is private

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

Not applicable

Title and more details about the data/document

All information except for the names and personal information of the participants

When the data will become available and for how long

6 months after the publication of the results

To whom data/document is available

Academic researchers by the reason

Under which criteria data/document could be used

If it is for scientific purposes

From where data/document is obtainable

They should send an Email to drmilmas@gmail.com, and after providing their reasons, the required information will be sent to them

What processes are involved for a request to access data/document

They should send an Email to drmilmas@gmail.com, and after providing their reasons, the required information will be sent to them

Comments