

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Epidural Analgesia and Dural Puncture Analgesia (Spinal/CSE) in Painless Natural Childbirth for Hospitalized Pregnant Women

Protocol summary

Study aim

Comparison of two analgesic methods, epidural and dural puncture, in painless natural childbirth among pregnant women admitted to Shahid Akbarabadi Hospital

Design

A phase 2, randomized, double-blind, parallel-group, controlled clinical trial will be conducted on 126 patients. Randomization will be performed using the Statistical Package for the Social Sciences (SPSS) software

Settings and conduct

This double-blind randomized trial at Shahid Akbarabadi Hospital (Nov 2023–Jun 2024) will compare standard epidural analgesia with dural puncture epidural (DPE) in pregnant women. Participants will be randomized to groups, and blinding will be maintained via randomized codes (A/B) and identical protocols for patients/assessors

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age over 18 and under 40 years; Full-term pregnancy American Society of Anesthesiologists (ASA) class I and II; Body mass index(BMI) between 20 and 25 kg/m²; Cervical dilation between 2 and 5 centimeters. Exclusion Criteria: Unwillingness to participate in the study; Cases complicated by brain or cardiovascular dysfunction; Patients who received opioid injections before the induction of anesthesia; Patients with spinal column disorders; Preterm delivery; adverse pregnancy outcomes; Contraindications for epidural block;

Intervention groups

Dural Epidural Puncture (DPE): Identification of the epidural space, Extraction of the stylet and confirmation of free flow of CSF (cerebrospinal fluid); Catheterization (insertion of the epidural catheter, injection of 3 ml of normal saline, withdrawal of the spinal needle, and fixation)

Main outcome variables

Satisfactory analgesia: time to achieve satisfactory

analgesia :Perceived pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191007045023N2**

Registration date: **2025-06-29, 1404/04/08**

Registration timing: **prospective**

Last update: **2025-06-29, 1404/04/08**

Update count: **0**

Registration date

2025-06-29, 1404/04/08

Registrant information

Name

Amineh Shafei nia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2635 2805

Email address

shafeinia.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-06, 1404/04/15

Expected recruitment end date

2026-03-21, 1405/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Epidural Analgesia and Dural Puncture Analgesia (Spinal/CSE) in Painless Natural Childbirth for Hospitalized Pregnant Women

Public title

Comparison of Epidural Analgesia and Dural Puncture Analgesia (Spinal/CSE) in Painless Natural Childbirth for Hospitalized Pregnant Women

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 and under 40 years Full-term pregnancy (gestational age between 37-42 weeks) American Society of Anesthesiologists (ASA) class I and II Body mass index between 20 and 25 kg/m² ervical dilation between 2 and 5 centimeters

Exclusion criteria:

Unwillingness to participate in the study Cases complicated by brain or cardiovascular dysfunction Patients who received opioid injections prior to the induction of anesthesia; Patients with spinal column disorders; Preterm delivery Patients with adverse pregnancy outcomes Contraindications for epidural block Patients who deliver within less than one hour from the placement of the epidural catheter

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

A table of random numbers will be used to randomize the study participants. To achieve this, the researcher will first determine the direction of movement in the table of random numbers and then place their finger on one of the cells. They will then proceed to move in the predetermined direction. The even numbers identified will be assigned to the conventional epidural group, and the odd numbers will be assigned to the DPE (dural puncture epidural) group. This process will continue until the required sample size is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study will be conducted as a double-blind trial. To maintain blinding, outcome assessors will remain unaware of the intervention type through the use of randomized codes (e.g., A and B), generated by an

independent system and kept confidential until the final analysis. Any identifiers linked to group assignments will be omitted during data collection. Furthermore, by ensuring identical interventions in both groups (in terms of appearance, administration method, and duration) and prohibiting information disclosure by the research team, patients will also remain blinded to their group allocation."

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Iran university of medical sciences

Street address

Next to Milad Tower, Hemat Highway ,Tehran

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Postal code

14496-14535

Approval date

2024-07-21, 1403/04/31

Ethics committee reference number

IR.IUMS.FMD.REC.1403.207

Health conditions studied**1****Description of health condition studied**

Analgesia

ICD-10 code

P04.0

ICD-10 code description

Newborn (suspected to be) affected by maternal anesthesia and analgesia in pregnancy, labor and delivery

Primary outcomes**1****Description**

Achieving the desired anesthesia

Timepoint

10 minutes after the interventions

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Maternal satisfaction with analgesia

Timepoint

after intervention

Method of measurement

Checklist

2

Description

Newborn Apgar score

Timepoint

1 and 5 minutes after birth

Method of measurement

Checklist

Intervention groups

1

Description

Intervention group: After identifying the epidural space in the DPE group, a 27-gauge Whitacre pencil-point needle will be inserted using the needle-through-needle technique, perforating the meninges. The needle stylet is then removed to observe the free flow of cerebrospinal fluid (CSF). Once confirmed, the spinal needle is withdrawn, and after injecting 3 mL of normal saline, the epidural catheter will be inserted. The catheter will be fixed in place similarly to the other group. If the aspiration test for blood or CSF is positive, the catheter will be reinserted, and the patient will be excluded from the study. After confirming negative aspiration, a loading dose of 5 micrograms of sufentanil and 10 mL of 0.1% ropivacaine will be administered slowly over 5 minutes with repeated aspirations. An infusion of 10 mL per hour of 0.1% ropivacaine with sufentanil (0.1 micrograms per mL) will then be initiated. In cases where the patient's VAS pain score exceeds 5, 5 mL of 0.1% ropivacaine with 5 micrograms of sufentanil will be administered as emergency analgesia 30 minutes after the initial bolus dose. The time of epidural initiation will be recorded, along with the time required to achieve a VAS score half of the baseline, the VAS score after ten minutes, and the time taken for the VAS score to drop below 3.

Category

Other

2

Description

Control group: In the group receiving conventional epidural anesthesia, 3 mL of normal saline is injected through the epidural needle, and an 18-gauge epidural catheter is placed into the epidural space, directed cephalad. After this step, the epidural needle is removed, and the epidural catheter is secured so that 3 centimeters remain within the epidural space.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi hospital

Full name of responsible person

Amineh Shafei nia

Street address

Molavi street, Molavi intersection, Ferdowsi garden station

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

deputy of research and thechnology

Street address

Iran University of Medical Sciences, 5th floor of the central headquarters, Hemat Highway, next to Milad Tower, Tehran

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Amineh Shafei nia

Position

Assistant Professor of Anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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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

Patient data is collected for research purposes only and cannot be published.

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

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

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

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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