# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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**
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Iran (Islamic Republic of)
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**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

**City**
Tehran

**Province**
Tehran

**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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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