Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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
City
Tehran
Province
Tehran
Postal code
14665354
Phone
+98 21 5560 6034
Email
shafeinia.a@iums.ac.ir

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
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Fax
+98 21 8862 2703
Email
info@iums.ac.ir
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
Street address
Molavi street, Molavi intersection, Ferdowsi garden station
City
Tehran
Province
Tehran
Postal code
116874351411
Phone
+98 21 5560 6034
Email
shafeinia.a@iums.ac.ir

Person responsible for scientific 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
Street address
Molavi street, Molavi intersection, Ferdowsi garden station
City
Tehran
Province
Tehran
Postal code
116874351411
Phone
+98 21 5560 6034
Email
shafeinia.a@iums.ac.ir

Person responsible for updating data

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
Street address
Molavi street, Molavi intersection, Ferdowsi garden station
City
Tehran
Province
Tehran
Postal code
116874351411
Phone
+98 21 5560 6034
Email
shafeinia.a@iums.ac.ir

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