

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison between spinal epidural and Dural puncture epidural in natural childbirth analgesia

Protocol summary

Study aim

Comparison between spinal epidural and Dural puncture epidural in natural childbirth analgesia in Kamali Hospital in karaj

Design

The clinical trial has intervention and comparison groups with parallel, double-blind, randomised groups, total of two groups on 98 patients, allocation of block randomization software.

Settings and conduct

EP: In order to perform an epidural in childbirth, a space lower than L2 should be selected. The needle enters the epidural space, then the catheter is fixed and the dose test is performed, and if it is confirmed, the drug is injected from the catheter site. DPE: using a spinal needle enters the CSF space and creates a hole without injecting the drug, and the continuation of the work and injection of the drug is the same as the epidural, with the difference that the drug is introduced gradually.

Participants/Inclusion and exclusion criteria

Entry Conditions: 1.pregnant women 37 to 40 weeks
2.women in the active stage of childbirth 3.vortex position Exit conditions: 1.Non_vortex position
2.Increased intracranial pressure 3.Dissatisfaction of the pregnant women 4.Malignancy

Intervention groups

According to the formula 98 people will enter the study in two groups and will be divided by random block allocation method using randomization software. They will be selected using blocks of four. Code A is the intervention group (using the DPE method) and code B is the comparison group (using the EP method). Then random codes will be generated for each of these blocks, then one of these blocks will be randomly selected and based on the sequence of letters A and B in the selected block, This random process of selecting blocks and assigning people to the intervention and comparison groups will continue until the desired sample size is reached.

Main outcome variables

1.dyspnea 2.seizure 3.hypotention 4.meningitis

General information

Reason for update

Acronym

EP / DPE

IRCT registration information

IRCT registration number: **IRCT20230903059336N1**

Registration date: **2023-09-22, 1402/06/31**

Registration timing: **prospective**

Last update: **2023-09-22, 1402/06/31**

Update count: **0**

Registration date

2023-09-22, 1402/06/31

Registrant information

Name

mina mohammadsalehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8803 5138

Email address

minasalehi74@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-05, 1402/08/14

Expected recruitment end date

2023-11-20, 1402/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison between spinal epidural and Dural puncture epidural in natural childbirth analgesia

Public title
Comparison between spinal epidural and Dural puncture epidural in natural childbirth analgesia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 pregnant women 37 to 40 weeks women in the active stage of childbirth vortex position
Exclusion criteria:
 Non-vortex position Increased intracranial pressure
 Bacteremia Local infection at the injection site
 Dissatisfaction of the pregnant women malignancy
 Cardiac heart failure Uncontrolled diabetes mellitus
 Coagulation disorder Anatomical deformity of the spine

Age
No age limit

Gender
Female

Phase
2-3

Groups that have been masked

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

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of random allocation of blocks will be divided using randomization software, blocks of four will be selected, code A will be the intervention group (using the DPE method) and code B will be the comparison group (using the EP method) and we will make six combinations of four. Then random codes will be generated for each of these blocks, then one of these blocks will be randomly selected, and based on the sequence of letters A and B in the selected block, eligible people will be assigned to treatment or comparison groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The method of block random assignment will be divided using randomization software, using blocks of four, code A will be the intervention group (using the DPE method) and code B will be the comparison group (using the EP method) and we will make six combinations of four. Then random codes will be generated for each of these blocks, then one of these blocks will be randomly selected and

based on the sequence of letters A and B in the selected block, the eligible people will be assigned to treatment or comparison groups. This process The random selection of blocks and assigning people to the intervention and comparison groups will continue until the desired sample size is reached. This method solves the problem of imbalance that may occur in simple randomization, so this study is two-sided. It is blind designed, thus the surgeon is aware of the status of assigning people to the study groups, but the data collector and analyzer as well as the patients are not aware of the status of assigning people to the study groups. For the study subjects, before random allocation, it is explained how the work process is, and they may receive one of the two treatments randomly, and the method used is not known to the subjects in advance, therefore, the patient does not know in which The group has been placed will be unaware, on the other hand, the data collectors and analysts will also be unaware of the patients' belonging to the treatment groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Alborz University of Medical Sciences

Street address

No6, 9th Avenue Valfajr Street South Sheikh Bahai

City

Tehran

Province

Tehran

Postal code

1437835174

Approval date

2023-08-27, 1402/06/05

Ethics committee reference number

IR.ABZUMS.REC.1402.146

Health conditions studied

1

Description of health condition studied

Analgesia childbirth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score

Timepoint

minutes of 0 5 10 15 20 30 45 60 90 120

Method of measurement

Asking person

2

Description

dyspnea

Timepoint

Immediately after birth

Method of measurement

counting

3

Description

Seizure

Timepoint

Immediately after birth

Method of measurement

Clinical symptoms

4

Description

Hypotention

Timepoint

Immediately after birth

Method of measurement

Manitor

5

Description

Meningitis

Timepoint

Immediately after birth

Method of measurement

Clinical symptom

Secondary outcomes

empty

Intervention groups

1

Description

Code A is the intervention group (using the DPE method) . We will have six quadruple combinations as (AA,BB) (AB,AB) (BA,BA) (AB,BA) (BB,AA) (BA,AB). Then random codes will be generated for each of these blocks, then one of these blocks will be randomly selected and based on the sequence of letters A and B in the selected block, the eligible people will be assigned to treatment or

comparison groups. This random process of selecting blocks and assigning people to the intervention and comparison groups will continue until the desired sample size is reached. Local anesthetics include: bupivacaine, levobupivacaine, and ropivacaine

Category

Treatment - Drugs

2

Description

code B is the comparison group (using the EP method). We will have six quadruple combinations as (AA,BB) (AB,AB) (BA,BA) (AB,BA) (BB,AA) (BA,AB). Then random codes will be generated for each of these blocks, then one of these blocks will be randomly selected and based on the sequence of letters A and B in the selected block, the eligible people will be assigned

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Karaj Kamali Hospital

Full name of responsible person

Mohammad Hossein Delshad

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Taleghani Avenue Shohada Square

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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
Karaj 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
Karaj University of Medical Sciences

Full name of responsible person
Mohammad Hossein Delshad

Position
Student

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Subspecialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
comparison between spinal epidural and dural puncture
epidural in natural childbirth analgesia
When the data will become available and for how long
after childbirth analgesia
To whom data/document is available

Student
Under which criteria data/document could be used
Evaluation and comparison of the results of two groups
From where data/document is obtainable
kamali hospital
What processes are involved for a request to access data/document
performing analgesia then following up the patients in terms of complications and other variables and finally analyzing data
Comments