Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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, levobopivacaine, 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
Street address
Taleghani Avenue Shohada Square
City
Karaj
Province
Alborz
Postal code
1437835174
Phone
+98 26 3442 7015
Email
m.delshad@abzums.ac.ir
Web page address
https://kamali.abzums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Mohammad Hossein Delshad
Street address
Koohestan Avenue 28Avenue
City
Karaj
Province
Alborz
Postal code
1437835174

Phone
+98 26 3419 7000
Email
info@abzums.ac.ir
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
Street address
No6 9tha Avenue Valfajr Street South Sheikh Bahai
City
Tehran
Province
Tehran
Postal code
1437835174
Phone
+98 21 8803 5138
Fax
Email
minasalehi74@yahoo.com
Web page address
http://abzums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Mohammad Hossein Delshad
Position
Professor of University
Latest degree
Subspecialist
Other areas of specialty/work
General Practitioner
Street address
No6 9th Avenue Valfajr Street South Sheikh Bahai
City
Tehran
Province
Tehran
Postal code
1437835174
Phone
+98 21 8803 5138
Fax
+98 21 8803 5138
Email
minasalehi74@yahoo.com
Web page address
http://abzums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Mohamad Hosein Delshad
Position
University professor
Latest degree
Subspecialist
Other areas of specialty/work
Biochemistry
Street address
Taleghani Street Shohada Square
City
karaj
Province
Alborz
Postal code
1437835174
Phone
+98 26 3442 7015
Fax
+98 26 3350 2347
Email
m.delshad@abzums.ac.ir
Web page address
http://kamalihospital.ir

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