Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

Comparison of the clinical results of the use of two spinal epidural methods and epidural puncture epidural in the process of natural childbirth analgesia - a randomized clinical trial

Protocol summary

Study aim

Determining and comparing the results of using two spinal epidural methods and epidural epidural puncture in the analgesia process of natural childbirth

Design

Clinical trial with intervention and control group, with parallel groups, double-blind, randomized, without phase on 98 patients, randomization software was used for randomization.

Settings and conduct

This study will be conducted by using two methods of analgesia, CSE and DPE, in the analgesia process of natural childbirth in Kamali Karaj Hospital. 98 people will enter the study in two groups and will be divided by the method of random block allocation 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 control group (using the CSE method). It is designed in a double-blind manner, collecting and analyzing data and the patients are unaware of the status of assigning people to the study groups. and only the surgeon is aware of the status of assigning people to the studied groups. In this research, a three-part questionnaire will be used to collect information, The required data is collected by the researcher

Participants/Inclusion and exclusion criteria

Entry criteria 1. 37 weeks to 40 weeks 2. Pregnant women giving birth naturally 3. Vertex position Exit criteria: 1. Non-vortex position 2. Coagulation disorders and homeostasis defects

Intervention groups

Intervention group: dural puncture epidural (DPE) Control group: spinal epidural analgesia (CSE)

Main outcome variables

1. The amount of pain during childbirth 2. Type of delivery (natural without tools / natural with the help of tools (vacuum) / ending in cesarean section) 3. Headache 4. Itching 5. Paresthesia 6. Urinary retention 7. Bishop Score 8. The length of the second stage of labor

General information

Reason for update

Amendment to inclusion criteria: The age range of participants was revised during the study to facilitate recruitment and improve eligibility. The age range was changed from 15–40 years to 18–45 years.

Acronym

Comparison of DPE and CSE

IRCT registration information

IRCT registration number: **IRCT20230310057671N1**
Registration date: **2023-04-16, 1402/01/27**
Registration timing: **prospective**

Last update: **2025-11-05, 1404/08/14**
Update count: **1**

Registration date

2023-04-16, 1402/01/27

Registrant information

Name

Ladan Keshavarzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

ladan93k@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-30, 1402/03/09

Expected recruitment end date
2023-07-31, 1402/05/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the clinical results of the use of two spinal epidural methods and epidural puncture epidural in the process of natural childbirth analgesia - a randomized clinical trial

Public title
Comparison of the clinical results of the use of two spinal epidural methods and epidural puncture epidural in the process of natural childbirth analgesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
37 weeks to 40 weeks pregnant women in normal labor vertex position
Exclusion criteria:
Non-vortex position Pregnant women's inability to maintain immobility during work (for example, Parkinson's disease) Coagulation disorders and homeostasis defects Increased intracranial pressure for any reason (space-occupying lesions) Local infection of the injection site and bacteremia
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
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
According to the formula of the sample size and after applying the entry and exit criteria, 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 CSE method). We will have 6 quadruple combinations as (AA,BB),(AB,BA),(BA,BA),(AB,AB),(BB,AA), and (BA,AB). Then for each of these Random code blocks will be generated. 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. This random process of selecting blocks and assigning people to intervention and comparison groups It will continue until the desired sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is designed in a double-blind manner, thus the surgeon is aware of the status of assigning people to the study groups, but the data collector and analyst as well as the subjects (patients) are not aware of the status of assigning people to the study groups. For the study subjects, before the random assignment, 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 beforehand, so the patient is not aware that in Which group is placed will be unknown (written consent will be obtained from all participants in the study). On the other hand, the data collector and analyzer will 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
No. 6, Unit 3, No. 6, Alley 9/4, 9th St., Valfajr Town, Tehran, Sheikh Bahai St.
City
Karaj
Province
Alborz
Postal code
1437835174
Approval date
2023-04-07, 1402/01/18
Ethics committee reference number
IR.ABZUMS.REC.1402.003

Health conditions studied

1

Description of health condition studied
Pregnant women giving birth naturally
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The amount of pain during childbirth is independent
Timepoint
0-5-10-15-20-30-45-60-90-120 min
Method of measurement
The intensity of the patient's pain during labor is measured by the numerical rating pain scale

2

Description
Type of delivery (natural without tools / natural with the help of tools (vacuum) / ending in caesarean section)
Timepoint
Time of delivery
Method of measurement
Description of the operation by the surgeon

3

Description
Headache
Timepoint
0 minutes, 12 hours, 24 hours
Method of measurement
Ask the person ، (After the analgesia intervention, it is only important for us whether the person has a headache at the mentioned times or not, the amount of headache that is low or high is not valuable for us in this study, for this reason, the person is only asked that Does he have a headache or not?

4

Description
itching
Timepoint
0 minutes, 5 minutes, 10 minutes
Method of measurement
Ask the person ، (After the analgesia intervention, it is only important for us if the person itches at the mentioned times or not, the amount of itching that is low or high has no value for us in this study, for this reason, the person is only asked that is it itchy or not)

5

Description
paresthesia
Timepoint
0 minutes, 60 minutes, 12 hours, 24 hours
Method of measurement
paresthesia ، (After the analgesia intervention, it is only important for us whether the person experiences paresthesia at the mentioned times or not, the amount of paresthesia that is low or high has no value for us in this study, for this reason, the person is only asked that Does it have paresthesia or not?

6

Description
urinary retention
Timepoint
12 hours, 24 hours
Method of measurement
Ask the person ، (After the analgesia intervention, it is only important for us if the person has urinary retention at the mentioned times or not, the amount of urinary retention that is low or high has no value for us in this study, that is why we only ask the person whether he has urinary retention or not)

7

Description
Bishop Score
Timepoint
0 min (immediately after the analgesia intervention)
Method of measurement
Bishop's score is determined by examining five characteristics: dilatation, effacement, descent, location of the cervix and consistency of the cervix based on the scoring system of the Bishop Score table. The scoring is calculated and recorded by the researcher in the laber

8

Description
Length of the second stage of labor
Timepoint
Starting from the complete dilatation of the cervix and continuing until the delivery of the baby, the analgesia intervention is performed before the complete dilatation of the cervix.
Method of measurement
We take time with the clock

Secondary outcomes

empty

Intervention groups

1

Description
Control group: In a group, combined spinal epidural analgesia (CSE) is performed in the following way: CSE is performed in stage I, in the first step, spinal analgesia is performed, in such a way that after prep and drape, spinal needle 25-28 in the L4-L5 intervertebral space, it enters the skin, passes through the dura mater and goes to the sub-arachnoid and enters the CSF space, after the CSF exit, the medicine will be injected within 3-5 seconds. Spinal Opiod: Fentanyl (dose: 15-25 micrograms) or sufentanil (dose: 10-5 micrograms) in the second step after prep and drape, the Touhy needle will go to the epidural space and a 5 cm catheter will be fixed in the epidural space and then the dose test will be done through Catheter is injected. Medicines: ropivacaine or bupivacaine with a concentration of 1%

(10-20 cc), lidocaine.

Category

Treatment - Surgery

2

Description

Intervention group: In the other group, dural epidural puncture (DPE) is performed in the following way: DPE is also performed in stage I, it is performed like the first spinal CSE, only with the difference that no drug is injected and the goal is only to puncture the dura. and then an epidural is performed and the catheter is fixed, here too no medication is administered until the mother enters the active phase of labor and her pain starts, then through the catheter first fentanyl (dose 15-25 micrograms) and then Rs. Vaccaine (10-20 cc) is administered. , and because of the hole created in the dura, the drug enters the CSF, even though he did not take medication during the spinal, but with the start of his epidural drugs, it seems as if the spinal is performed at the same time, in DPE, unlike CSE, not all fentanyl directly enters the CSF and It is gradually absorbed (in general, the drugs are the same in both methods, only the method and time of drug absorption are different, which differentiates the side effects of these two methods) The percentage of drugs in both methods is diluted based on the patient's BMI.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Karaj Kamali hospital

Full name of responsible person
Maryam Hashem Nejad

Street address
Kamali Medical Education Center, kamali street, shahada square, shahid behshti street, karaj city, alborz province

City
Karaj

Province
Alborz

Postal code
1234567890

Phone
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Email
Kamali@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
Shahram Sayyadi

Street address
Alborz University of Medical Sciences, Administrative Town, North Taleghani Boulevard, Taleghani Square, karaj

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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
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
NO 4, The highly specialized pain clinic of Maryam Hospital, street West Arghwan, 45 meter Golshahr, Alborz province,karaj

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Province
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Mohammad Hossein Delshad
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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NO 4, The highly specialized pain clinic of Maryam Hospital, street West Arghwan, 45 meter Golshahr, Alborz province,karaj
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Email
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Web page address
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Person responsible for updating data

Contact

Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Ladan Keshavarzi
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Anesthesiology
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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts one year after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Any kind of scientific or research use
From where data/document is obtainable
Laden agriculture Receive data via email below ladan.keshavarzi@yahoo.com
What processes are involved for a request to access data/document
After receiving the request email, the request will be answered within a maximum of two months.
Comments
No other explanation