Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of dural epidural puncture technique in comparison with combined epidural-spinal and epidural techniques in painless delivery and the consequences of labor, mother and newborn

Protocol summary

Study aim

Evaluation of the effect of dural epidural puncture technique in comparison with combined epidural-spinal and epidural techniques in painless delivery and the consequences of labor, mother and newborn

Design

A randomized clinical trial, two groups of 30; Epidural : determination of epidural space using loss of resistance to saline, Dural epidural puncture: determination of dural puncture in the axis of epidural needle with needle-through-needle technique and Epidural-spinal : combination of epidural and spinal anesthesia, randomized using the random numbers table.

Settings and conduct

Pregnant women candidates for painless delivery referred to Maryam Hospital with the conditions of entry into the study will be randomly placed in three groups of 30 in one of the Epidural /Dural epidural puncture/Epidural-spinal groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with ASA Class I, II ; Gestation age 38-42 weeks; Candidate for painless delivery. Exclusion criteria: Contraindications for performing neuraxial analgesia techniques; People who are unable to maintain the position when the needle is inserted; History of spine surgery; Presence of wound and infection at the needle entry site.

Intervention groups

Epidural group: The pregnant woman is placed in a sitting position, then in the L2-L3 or L3-L4 regions with a midline approach, with a 17 gage epidural needle the epidural space is determined using loss of resistance to saline. Dural epidural puncture group: With the needle-through-needle technique, a Whitacre 25 gage spinal needle is used to confirm dural puncture in the axis of the epidural needle. Epidural-spinal group: Epidural anesthesia is performed like the epidural group and spinal anesthesia using Quincke 25 gage needle. In all groups, 8-12 ml of ropivacaine 0.1% is used.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211112053042N4**
Registration date: **2022-09-29, 1401/07/07**
Registration timing: **prospective**

Last update: **2022-09-29, 1401/07/07**
Update count: **0**

Registration date

2022-09-29, 1401/07/07

Registrant information

Name

Mohammad Hossein Delshad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3350 2347

Email address

m.delshad@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-06, 1401/07/14

Expected recruitment end date

2022-12-20, 1401/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of dural epidural puncture technique in comparison with combined epidural-spinal and epidural techniques in painless delivery and the consequences of labor, mother and newborn

Public title

The effect of dural epidural puncture technique in comparison with combined epidural-spinal and epidural techniques in painless delivery and the consequences of labor, mother and newborn

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women with ASA Class I, II Gestation age 38-42weeks Singleton Vertex presentation Entering the active phase of labor with dilatation less than 5 cm A candidate for painless delivery Pregnant women with consent to participate in the project

Exclusion criteria:

Pregnant women with lack of consent to participate in the project History of back surgery Diseases related to pregnancy such as gestational hypertension, preeclampsia, gestational diabetes Contraindications for performing neuraxial analgesia techniques Known fetal anomaly A condition with an increased risk of cesarean section, such as a history of previous cesarean section, a history of uterine rupture Diseases of the central nervous system Allergy to the drugs used in the study Coagulation disorders, decreased platelet count Local or systemic infection The presence of blood or cerebrospinal fluid in the epidural catheter during the procedure History of drug abuse People who are unable to maintain the position when the needle is inserted History of spine surgery Presence of wound and infection at the needle entry site

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Study subjects will be divided into three groups, epidural , dural epidural puncture and combined epidural-spinal , using a simple randomization method and using a table of random numbers. First, each person is assigned a number. Then, using the table of random numbers, each selected number is randomly assigned to one of the groups, and this work continues until the number of people in each group is completed. Therefore, the researcher will not have the authority to change the status of the assignment of people or to predict it. Randomization concealment will be done by a third person who does not participate in other stages of the intervention.

Blinding (investigator's opinion)

Not blinded

Blinding description

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

second floor, Deputy of Research and Technology, Saffarian Alley, 45 meters from Golshahr, Karaj.

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2022-09-23, 1401/07/01

Ethics committee reference number

IR.ABZUMS.REC.1401.168

Health conditions studied

1

Description of health condition studied

Painless delivery

ICD-10 code

O80

ICD-10 code description

Encounter for full-term uncomplicated delivery

Primary outcomes

1

Description

Pain

Timepoint

Before the start of the procedure, 5, 10, 15, 30, 45, 60, 90, 120, 180, 240 minutes after the procedure, cervical

dilatation 6 cm, cervical dilatation 10 cm, immediately after the exit of the fetus.

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Analgesia onset time

Timepoint

When with the first bolus injection, the pain score is <= 3 based on VAS.

Method of measurement

Ask the patient

2

Description

Movement block

Timepoint

every 15 minutes

Method of measurement

Based on scoring Bromage criteria

3

Description

Sensory block

Timepoint

every 15 minutes

Method of measurement

Sensory block at S2 and T10 levels

4

Description

Systolic blood pressure

Timepoint

Before the procedure, 5, 10, 15, 30, 45, 60, 75, 105, 135, 165 minutes later

Method of measurement

Measurement with pressure gauge

5

Description

Diastolic blood pressure

Timepoint

Before the procedure, 5, 10, 15, 30, 45, 60, 75, 105, 135, 165 minutes later

Method of measurement

Measurement with pressure gauge

6

Description

Heart rate

Timepoint

Before the procedure, 5, 10, 15, 30, 45, 60, 75, 105, 135, 165 minutes later

Method of measurement

Measurement with non-invasive devices

7

Description

Oxygen saturation

Timepoint

Before the procedure, 5, 10, 15, 30, 45, 60, 75, 105, 135, 165 minutes later

Method of measurement

Pulse Oximetry

8

Description

Apgar score

Timepoint

At 1 and 5 minutes after birth

Method of measurement

Neonatal specialist examination

Intervention groups

1

Description

The first intervention group: Dural epidural puncture group: With the needle-through-needle technique, a Whitacre 25 gage spinal needle is used to confirm dural puncture in the axis of the epidural needle. 8-12 ml of ropivacaine 0.1% is used.

Category

Prevention

2

Description

The second intervention group: Epidural anesthesia is performed like the epidural group and spinal anesthesia using Quincke 25 gage needle. 8-12 ml of ropivacaine 0.1% is used.

Category

Prevention

3

Description

Control group: Epidural group: The pregnant woman is placed in a sitting position, then in the L2-L3 or L3-L4 regions with a midline approach, with a 17 gage epidural needle the epidural space is determined using loss of resistance to saline. 8-12 ml of ropivacaine 0.1% is used.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Maryam Hospital

Full name of responsible person
Mohammad Hossein Delshad MD.
Street address
Arghvan West, 45 meter Golshahr St.
City
Karaj
Province
Alborz
Postal code
3198683639
Phone
+98 26 3350 9323
Email
m.delshad@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Hatam Godini P.H.D
Street address
Saffarian alley, 45 meters from Golshahr, Karaj
City
Karaj
Province
Alborz
Postal code
3198764653
Phone
+98 26 3464 3705
Email
h.godini@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 MD.
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Arghavan Gharbi, 45 meters from Golshahr Street, Karaj, Alborz Province
City
Karaj
Province
Alborz
Postal code
3198683639
Phone
+98 26 3350 2347
Email
m.delshad@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 MD.
Position
Assistant professor
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Person responsible for updating data

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Mohammad Hossein Delshad MD.
Position
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Phone

+98 26 3350 2347

Email

m.delshad@abzums.ac.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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published.

To whom data/document is available

Research centers and faculty members

Under which criteria data/document could be used

At the request of the researcher and faculty members

From where data/document is obtainable

Send email to the scientific respondent

What processes are involved for a request to access data/document

Within two months from the time of requesting and sending the email, the documents will be sent to the mentioned people

Comments