

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of the Fetal Heart Rate changes between Epidural Analgesia Delivery and Combined Spinal-Epidural Analgesia Delivery

Protocol summary

Study aim

Comparison of the Fetal Heart Rate changes between Epidural Analgesia Delivery and Combined Spinal-Epidural Analgesia Delivery

Design

One hundred healthy mother with term and singleton pregnancy candidate for NVD with neuroaxial analgesia, entered the study after obtaining written informed consent, will be placed respectively and randomly into two groups of 50 (combined or epidural).

Settings and conduct

Pregnant women in Taleghani hospital in Tabriz, are randomly and blinded assigned into two groups. Two technicians who are blind to the analgesia record the fetal heart rate, fetal motion and then the Apgar score.

Participants/Inclusion and exclusion criteria

Entrance criteria: Ability to have a normal vaginal delivery The delivery to be in the active phase. Exit criteria: Missing consent , Inability of the pregnant to remain motionless while doing work, Coagulation disorder, Increased intracranial pressure, Local infections. History of sensitivity, Acute lesions of the CNS, Hemodynamic Disorders, Cardiovascular Diseases, Embryonic distress, GA <37 w, Abnormal fetal presentations, History of C/S - BMI > 40

Intervention groups

1. First intervention group (Epidural analgesia group): First for the test dose: 3 ml of lidocaine 1.5%, 50 µg of fentanyl and 2.5 mg of bupivacaine are used. Then as a preservative dose 6 cc / h from the solution is injected through the catheter. 2. Second intervention group (Combined analgesia group): First 1.5ml of the same solution is injected and then the epidural block will be performed using the same method of epidural group.

Main outcome variables

Reducing labor pain and reducing C/S frequency due to maternal fears of normal labor pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180626040241N1**

Registration date: **2018-09-22, 1397/06/31**

Registration timing: **retrospective**

Last update: **2018-09-22, 1397/06/31**

Update count: **0**

Registration date

2018-09-22, 1397/06/31

Registrant information

Name

Nabiha Al Darir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3441 1230

Email address

nonitahasan@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-06, 1397/04/15

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

2017-12-22, 1396/10/01

Actual recruitment end date

2018-06-22, 1397/04/01

Trial completion date

empty

Scientific title

Comparison of the Fetal Heart Rate changes between Epidural Analgesia Delivery and Combined Spinal-Epidural Analgesia Delivery

Public title

Effects of Epidural and Combined Analgesia on the Fetal Heart Rate.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Ability to have a normal vaginal delivery Existence of labor pain and the delivery is in the active phase. Pregnant mother wants to reduce labor pain itself. Consent of the patient and her husband.

Exclusion criteria:

Missing consent of pregnant woman or spouse. Inability of the pregnant to remain motionless while doing work(e.g. Parkinson disease). Coagulation disorder Increased intracranial pressure (SOL). Local infections at the puncture site History of sensitivity to analgesics and other medication used in this investigation Acute lesions of the CNS Hemodynamic Disorders (e.g. hypotension or Hypovolemia). Cardiovascular Diseases that reduce the cardiac output Embryonic distress. GA <37 w Abnormal fetal presentations History of C/S or any surgery on the uterus BMI > 40

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The pregnant woman in this study gives consent to the Analgesia while she is blind from its type. A trained Anesthesia technician and an midwife who are blinded from the analgesia type monitor and record the fetal heart rate, fetal motion and then the Apgar score.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Central Office of the University of Medical Sciences, Golgast Street, Azadi Avenue, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166615739

Approval date

2018-06-11, 1397/03/21

Ethics committee reference number

IR.TBZMED.REC.1397.240

Health conditions studied

1

Description of health condition studied

-

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fetal heart rate

Timepoint

5 min before performing the analgesia and then 5, 10, 20,40, 60 min after and then every 30 min until the exit of the fetus

Method of measurement

With the use of the fetal monitor

2

Description

Fetal motion

Timepoint

5 min before performing the analgesia and then 5, 10, 20,40, 60 min after and then every 30 min until the exit of the fetus

Method of measurement

With the use of the fetal monitor

3

Description

Apgar scor

Timepoint

After the delivery at the minute 1 and 5

Method of measurement

calculating

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (Epidural analgesia group): The neuroaxial block is performed with epidural needle number 18 G . First, for the test dose: 3 ml of lidocaine 1.5%, 50 µg of fentanyl and 2.5 mg of bupivacaine are used. Then as a preservative dose 6 cc / h from this solution is injected through the catheter.

Category

Treatment - Drugs

2

Description

Intervention group (Combined spinal-epidural analgesia group): First with a spinal needle 25G, the spinal block with 1.5ml of the same solution is performed and then the epidural block will be performed using the same method of epidural group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital in Tabriz

Full name of responsible person

Dr. Hojjat Pourfathi

Street address

Railway square, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

000

Phone

+98 41 3442 4423

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Email

taleghani.hos@tbzmed.ac.ir

Web page address

<https://taleghanihosp.tbzmed.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. jouyban

Street address

Central Office of the University of Medical Sciences,
Golgast Street, Azadi Avenue, Tabriz

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Fax

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Email

Research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Nabiha aldarir

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

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5178757395

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Nabiha aldarir

Position

Intern

Latest degree

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Person responsible for updating data

Contact

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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

We will act according to the laws of the Ministry of Health and Medical Education and Tabriz University of Medical Sciences

When the data will become available and for how long

We will act according to the laws of the Ministry of Health and Medical Education and Tabriz University of Medical Sciences

To whom data/document is available

We will act according to the laws of the Ministry of Health and Medical Education and Tabriz University of Medical Sciences

Under which criteria data/document could be used

We will act according to the laws of the Ministry of Health and Medical Education and Tabriz University of Medical Sciences

From where data/document is obtainable

Central Library of Tabriz University of Medical Sciences and Faculty of Medicine

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

We will act according to the laws of the Ministry of Health and Medical Education and Tabriz University of Medical Sciences

Comments