Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Maternal Hemodynamic between Epidural Analgesia Delivery and Combined Spinal-Epidural Analgesia Delivery

Protocol summary

Study aim
Comparison of the Maternal Hemodynamic 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 (epidural or combined). Tow technicians who are blind to the analgesia record the maternal V/S and occurence of hypotension.

Participants/Inclusion and exclusion criteria
Entrance criteria: Ability to have a normal vaginal delivery The delivery to be in the active phase. Exit criteria: Dissatisfaction, 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
First 500cc of Ringer Lactate fluid will be prescribed. The neuroaxial blocks will be performed from the intervertebral space L3-4 or L4-5 with a (lack of resistance) technique. In the epidural group, the block with epidural needle number 18 G is performed. First, for the test dose: 3 ml of lidocaine 1.5%, 50 µg of fentanyl and 2.5 mg of bupivacaine is used. Then as a preservative dose 6 cc / h from the solution is injected through the catheter. In the combination group, first with 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.

Main outcome variables
Reducing labor pain and C/S; Choosing an analgesic with the least complication

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180626040240N1**
Registration date: **2018-08-01, 1397/05/10**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-01, 1397/05/10**
Update count: **0**

Registration date
2018-08-01, 1397/05/10

Registrant information

Name
Mhd Mahdi Al Miski

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3441 1230

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-15, 1397/03/25

Expected recruitment end date
2018-08-23, 1397/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Maternal Hemodynamic between Epidural Analgesia Delivery and Combined Spinal-Epidural Analgesia Delivery

Public title
Comparison of the Maternal Hemodynamic between Epidural Analgesia Delivery and Combined Spinal-Epidural Analgesia Delivery
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 it self. Consent of the patient and her husbend.
Exclusion criteria:
Maternal or spouse dissatisfaction. 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 - BMI> 40 Abnormal fetal presentations History of C/S or any surgery on the uterus History of 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**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
The pregnant gives consent to the Analgesia while she is blind to its type. Trained anesthetize technician and an accoucheuse who are blind to the analgesia type monitor and record the maternal hemodynamic
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.1379.241

Health conditions studied

1

Description of health condition studied
Analgesia for normal vaginal delivery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Maternal blood pressure
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 a Barometer

2

Description
Maternal pulse 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 a monitor device

3

Description

Maternal Oxygen Saturation

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 a pulse oximetry

Secondary outcomes

1

Description

Apgar score

Timepoint

Minuts 1 and 5

Method of measurement

Calculating

Intervention groups

1

Description

Intervention group: Epidural analgesia 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 is 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 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

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East Azarbaijan

Postal code

0

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Fax

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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

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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

Mohamad Mahdi Almiski

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

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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