# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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 husbend.
**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**
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**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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**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**
Shayan mehr dorm, eqbal aazar ave, Resalat Street

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Nabiha aldarir

**Position**
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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**