# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Nov 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)

**Phone**
+98 41 3441 1230

**Email address**
saidmohamad10@tbzmed.ac.ir

**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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

0

**Phone**

+98 41 3442 4423

**Fax**

+98 41 3442 4882

**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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

0

**Phone**

+98 41 3335 7310

**Fax**

+98 41 3334 4280

**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**

Mohamad Mahdi Almiski

**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
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5178757395
**Phone**
+98 41 3441 1230
**Email**
dr.mahdi.almiski@gmail.com

## Person responsible for scientific 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
**Street address**
Shayan mehr dorm, eqbal aazar ave, Resalat Street
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5178757395
**Phone**
+98 41 3441 1230
**Email**
dr.mahdi.almiski@gmail.com

## Person responsible for updating data

**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
**Street address**
Shayan mehr dorm, eqbal aazar ave, Resalat Street
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5178757395
**Phone**
+98 41 3441 1230
**Email**
dr.mahdi.almiski@gmail.com

## 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**