# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Nov 2026

## Comparison of the complications of Labour analgesia with Spinal or Combined Spinal-Epidural Analgesia

### Protocol summary

**Study aim**
Comparison of the complications of Labour analgesia with Spinal or Combined Spinal-Epidural Analgesia

**Design**
clinical trial with Two groups of 45 in parallel, consecutive, randomised

**Settings and conduct**
Comparison of the complications of Labour analgesia with Spinal or Combined Spinal-Epidural Analgesia in the delivery section of Taleghani hospital in Tabriz.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: There is a possibility of natural birth; There is labor pain and active delivery phase; mother's consent to reduce delivery paint. Exclusion criteria: mother's disinclination to participate; Inability to maintain immobility during procedure; Coagulation disorders and defects in homeostasis; Increased intracranial pressure for any reason; Frank infection at the needle site; Hypersensitivity to local anesthetics or other medications using in this methods; Acute lesions of the central nervous system; Maternal hemodynamic instability (hypovolemia, hypotension) ; Heart diseases that cardiac output is severely limited; fetal distress.

**Intervention groups**
Spinal analgesia group: during delivery 25 to 50 microgram intrathecal fentanyl injection to L4-L5 as opioid combined with 2.5 milligram bupivacaine to enhance analgesia quality and duration Combined spinal-epidural group: during delivery intrathecal injection of 3 millimeter 1.5% lidocaine combined with 8 to 10 milligram of 5 mg/ml bupivacaine with 0.0625 saturation with 50 microgram fentanyl injection following by 25 to 50 microgram fentanyl injection to subarachnoid space combined with 2.5 milligram bupivacaine to

**Main outcome variables**
hypotension, nausea, vomiting, depresion of respiration, urinary incontinance, complete spinal block, drop of FHR

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20160103025821N4**
Registration date: **2018-07-17, 1397/04/26**
Registration timing: **retrospective**

Last update: **2018-07-17, 1397/04/26**
Update count: **0**

**Registration date**
2018-07-17, 1397/04/26

**Registrant information**

**Name**
Hojjat Pourfathi

**Name of organization / entity**
Tabriz university of medical sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 41 3334 1994

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

**Recruitment status**
**Recruitment complete**

**Funding source**

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

**Expected recruitment end date**
2018-07-11, 1397/04/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of the complications of Labour analgesia with Spinal or Combined Spinal-Epidural Analgesia

**Public title**
Comparison of the complications spinal analgesia with Spinal-Epidural Analgesia in natural delivery

**Purpose**
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
There is a possibility of natural birth mother's consent to reduce delivery pain

**Exclusion criteria:**
mother's disinclination to participate Inability to maintain immobility during procedure Coagulation disorders and defects in homeostasis Increased intracranial pressure for any reason Frank infection at the needle site Hypersensitivity to local anesthetics or other medications using in this methods Acute lesions of the central nervous system Maternal hemodynamic instability (hypovolemia, hypotension) Heart diseases that cardiac output is severely limited fetal distress

**Age**
No age limit

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **90**

**Randomization (investigator's opinion)**
N/A

**Randomization description**

**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 the research and technology department, Tabriz University of Medical sciences

**Street address**
Research department, Daneshghah street, Tabriz

**City**
Tabriz

**Province**
East Azarbaijan

**Postal code**
5166615953

**Approval date**
2018-06-11, 1397/03/21

**Ethics committee reference number**
IR.TBZMED.REC.1397.233

## Health conditions studied

### 1

**Description of health condition studied**
the complications of Labour analgesia

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Hypotension

**Timepoint**
Immediately after the intervention, after 5 minute, after 10 minute, after 20 minute, after 40 minute, after 60 minute, after 1.5 hour, after 2 hour, after 3 hour, ...

**Method of measurement**
Monitoring, Sphygmomanometer tool

### 2

**Description**
Pruritus

**Timepoint**
Immediately after the intervention, after 5 minute, after 10 minute, after 20 minute, after 40 minute, after 60 minute, after 1.5 hour, after 2 hour, after 3 hour, ...

**Method of measurement**
History

### 3

**Description**
Headache

**Timepoint**
Immediately after the intervention, after 5 minute, after 10 minute, after 20 minute, after 40 minute, after 60 minute, after 1.5 hour, after 2 hour, after 3 hour, ...

**Method of measurement**
History

### 4

**Description**
Backpain

**Timepoint**
Immediately after the intervention, after 5 minute, after 10 minute, after 20 minute, after 40 minute, after 60 minute, after 1.5 hour, after 2 hour, after 3 hour, ...

**Method of measurement**
History

### 5

**Description**
Urinary incontinence
**Timepoint**
Immediately after the intervention, after 5 minute, after 10 minute, after 20 minute, after 40 minute, after 60 minute, after 1.5 hour, after 2 hour, after 3 hour, ...
**Method of measurement**
History

### 6

**Description**
Respiratory depression
**Timepoint**
Immediately after the intervention, after 5 minute, after 10 minute, after 20 minute, after 40 minute ,after 60 minute, after 1.5 hour, after 2 hour, after 3 hour, ...
**Method of measurement**
PHysical examination

### 7

**Description**
Complete Spinal Block
**Timepoint**
Immediately after the intervention, after 5 minute, after 10 minute, after 20 minute, after 40 minute, after 60 minute, after 1.5 hour, after 2 hour, after 3 hour, ...
**Method of measurement**
PHysical examination

### 8

**Description**
Fetal heart rate
**Timepoint**
Before the intervention, Immediately after the intervention, Every 5 minutes until delivery, Immediately after delivery
**Method of measurement**
PHysical examination

## Secondary outcomes

### 1

**Description**
Studied groups
**Timepoint**
mmediately after the intervention, after 5 minute,after10 minute,after20minute,afer40minute,after60minute,afer1.5hour,after2hour,after3hour,...
**Method of measurement**
check list

## Intervention groups

### 1

**Description**
Intervention group: Spinal analgesia group: during delivery 25 to 50 microgram intrathecal fentanyl injection to L4-L5 as opioid combined with 2.5 milligram bupivacaine to enhance analgesia quality and duration
**Category**
Prevention

### 2

**Description**
Intervention group: Combined spinal-epidural group: during delivery intrathecal injection of 3 millimeter 1.5% lidocaine combined with 8 to 10 milligram of 5 mg/ml bupivacaine with 0.0625 saturation with 50 microgram fentanyl injection following by 25 to 50 microgram fentanyl injection to subarachnoid space combined with 2.5 milligram bupivacaine to
**Category**
Prevention

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Tabriz Taleghani hospital
**Full name of responsible person**
Dr. Hojjat Pourfathi
**Street address**
Taleghani hospital, Rah ahan square, Tabriz
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
34424882
**Phone**
+98 41 3442 4425
**Email**
pourfathih@tbzmed.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Tabriz University of Medical Sciences
**Full name of responsible person**
Dr. abolghasem jouyban
**Street address**
Tabriz University of Medical Sciences, Daneshgah Street, Tabriz
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
3344280 0413
**Phone**
+98 41 3335 7310
**Email**

ajouyban@hotmail.com

**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**

Dr.hojjat Pourfathi

**Position**

Assistant Professor in Anesthesiology

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Talghani hospital, Rah ahan square, Tabriz

**City**

Tabriz

**Province**

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**Postal code**

34424882

**Phone**

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**Email**

pourfathih@tbzmed.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.hojjat pourfathi

**Position**

Assistant Professor in Anesthesiology

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.hojjat pourfathi

**Position**

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**Latest degree**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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**

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