Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 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)

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+98 41 3334 1994

Email address
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Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2018-07-11, 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
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Tabriz
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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

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34424882

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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

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Position

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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