

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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, Daneshgah 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

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

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 milligram 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

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East Azarbaijan

Postal code

3344280 0413

Phone

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr.hojjat pourfathi

Position

Assistant Professor in Anesthesiology

Latest degree

Specialist

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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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