

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

A comparison of spinal and epidural analgesia for labor pain and maternal and neonatal outcomes

Protocol summary

Summary

After obtaining the informed consent from the women who were hospitalized for normal vaginal delivery in the maternity of Ghaem and Imam Reza hospitals from 2017 to 2019 and had inclusion criteria were randomly assigned to two groups for performing labor analgesia. The inclusion criteria: single or twin term pregnancy, primi and multiparity, cephalic presentation, not use of narcotic drugs, no history of bleeding disorders, normal platelet and INR. Pregnant women were assigned in two groups based on random table. In epidural group (A), epidural needle No.17 is inserted between L3-L4 space. if the blood and CSF are not aspirated, then 4 cc bupivacaine 0.5% with 4 cc normal saline and 50 microgram of Fentanyl will injected in this space. In spinal group (B), spinal needle No.25 is inserted between L3-L4 space and 0.75 cc bupivacaine with 0.5 cc Fentanyl will injected in this space. After injection of regional analgesics, the patient will be evaluated every 5 minutes in first 15 minutes. Pain score will be evaluated by visual analogue scale. Motor block will be evaluated based on Bromage scale. The complications like nausea and vomiting, pruritus, hypotension will be evaluated during the study. After delivery, the neonate will be assessed for 5th Apgar score, need to resuscitation, and NICU admission.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015053022473N1**
Registration date: **2017-10-22, 1396/07/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-22, 1396/07/30

Registrant information

Name

Leila Pourali

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 2477

Email address

pouralil@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of spinal and epidural analgesia for labor pain and maternal and neonatal outcomes

Public title

A comparison of spinal and epidural analgesia for labor pain and maternal and neonatal outcomes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: single or twin term pregnancy, primi

and multiparity, cephalic presentation, not use of narcotic drugs, no history of bleeding disorders, normal platelet and INR, no fetal distress, and mother's request for regional labor analgesia. Exclusion criteria: the mother's unwillingness to continue the study.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

since this is an interventional study, in order to minimize the systematic error, it will be performed as double-blind. Both the patient and the person who completed the questionnaire were blind about assigning the groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Azadi square, Mashhad University of Medical Sciences

City

Mashhad

Postal code

Approval date

2017-06-14, 1396/03/24

Ethics committee reference number

IR.MUMS.fm.REC.1396.144

Health conditions studied

1

Description of health condition studied

Labor analgesia

ICD-10 code

O80-O84

ICD-10 code description

Delivery

Primary outcomes

1

Description

Labor analgesia

Timepoint

every 15 min

Method of measurement

by visual analogue scale

Secondary outcomes

1

Description

need to resuscitation

Timepoint

after birth

Method of measurement

Neonate's respiratory and cardiac status

2

Description

Motor block

Timepoint

every 15 min

Method of measurement

Bramage scale

3

Description

duration of delivery

Timepoint

after birth

Method of measurement

based on time (min)

4

Description

duration of second stage of labor

Timepoint

after birth

Method of measurement

based on time (min)

5

Description

Neonate's Apgar score

Timepoint

after birth

Method of measurement

Apgar score

Intervention groups

1

Description

Intervention 1: At first, one liter of ringer lactate solution will be infused. Under sterile technique, injection will be done at decubitus position. The epidural needle No.17 is inserted between L3-L4 or L4-L5 space. If the blood and CSF are not aspirated, then 3 cc lidocaine 1% was injected. Then, through catheter, 4 cc bupivacaine 0.5% with 4 cc normal saline and 50 microgram of Fentanyl will be injected in this space.

Category

Treatment - Drugs

2

Description

Intervention 2: At first, one liter of ringer lactate solution will be infused. Under sterile technique, injection will be done at decubitus position. The spinal needle No.25 is inserted between L3-L4 or L4-L5 space; after extrusion of 1 cc of csf, 3.75 cc bupivacaine and 0.5 cc Fentanyl (25 microgram) which is diluted in 0.75 of normal saline will be injected in this space.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem and Imam Reza Hospitals

Full name of responsible person

Leila Pourali

Street address

Mashhad, Ahmadabad St., Ghaem Hospital

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Mashhad University of Medical Sciences

Full name of responsible person

Leila Pourali

Street address

Ahmadabad Street, Ghaem Hospital, Department of Obstetrics and Gynecology

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Leila Pourali

Position

Assistant professor, Department of Obstetrics and Gynecology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Leila Pourali

Position

Assistant professor, Department of Obstetrics and Gynecology

Other areas of specialty/work

Street address

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty