Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 resucitation

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 decabitus 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 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 decabitus 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 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
Street address
Ahmadabad Street, Ghaem hospital
City
Mashhad
Postal code
Phone
+98 51 3801 2477
Fax
Email
Pouralil@mums.ac.ir
Web page address

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
Ahmadabad Street, Ghaem hospital
City
Mashhad
Postal code
Phone
+98 51 3801 2477
Fax
Email
pouralil@mums.ac.ir
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