Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

comparison Spinal and epidural anesthesia with bupivacaine and pethidine in Painless Childbirth

Protocol summary

Summary

Objective: To compare the effect of the spinal pethidine with epidural bupivacaine in relief of labor pain. Population: patients were randomly divided into two groups. The first group of were consists of 25 patients who received spinal anesthesia and the second group were 25 patients that received an epidural one. Sample size: 25 pregnant women who were candidates for vaginal delivery with epidural bupivacaine and 25 cases with spinal anesthesia with pethidine. Methods and materials: at first about 500-1000cc serum(ringer) were infused for all the patients of pethidine group In the first group for prevention of nausea and vomiting metoclopramide (mg100) dexamethasone(8mg) was injected intravenously. The patient was placed in a sitting position and a 25-gauge needle with the tip bent(Aspanyal)were used , 25 mg pethidine +1/5 mgdextrose 10% of the total volume 2cc (hyper time being) was injected into the subarachnoid space. In the second group (epidural anesthesia) epidural catheter 20 in the L3 - L4 space were used when the cervix is 4cm.The bolus dose 0/125 percent (15cc) of bupivacaine and fentanyl3/12 microgram/cc in three divided dose every 5 minutes were used. The dose was repeated if the effect of drug were disappeared before delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013060312701N5**
Registration date: **2013-06-13, 1392/03/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-06-13, 1392/03/23

Registrant information

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Mohammad Forozeshfard
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2013-01-03, 1391/10/14

Expected recruitment end date

2013-07-05, 1392/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison Spinal and epidural anesthesia with bupivacaine and pethidine in Painless Childbirth

Public title

Spinal and epidural anesthesia with bupivacaine and pethidine in Painless Childbirth

Purpose

Supportive

Inclusion/Exclusion criteria

The study group were all pregnant women who were candidate for the normal vaginal delivery and they had no underlying disease consists of heart disease and asthma.

Age
No age limit
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
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
Semnan University of Medical Services
Street address
Semnan University of Medical Services
City
semnan
Postal code
Approval date
2012-08-07, 1391/05/17
Ethics committee reference number
5845/16/91

Health conditions studied

1

Description of health condition studied
Single spontaneous delivery
ICD-10 code
O80
ICD-10 code description
Single spontaneous delivery

Primary outcomes

1

Description
Analgesia
Timepoint
Before and after the intervention to end delivery process
Method of measurement
Numeric Rating Pain Scale

Secondary outcomes

1

Description
Changes in blood pressure
Timepoint
From start to finish the process of intervention delivery
Method of measurement
Pressure gauge

2

Description
Nausea and vomiting
Timepoint
From start to finish the process of intervention delivery
Method of measurement
Nausea, and stomach contents during delivery

3

Description
Respiratory depression
Timepoint
From start to finish the process of intervention delivery
Method of measurement
Observational

Intervention groups

1

Description
The first group of 25 patients who received spinal anesthesia.
Category
Treatment - Drugs

2

Description
The second group of 25 patients who received an epidural.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin hospital
Full name of responsible person
Forozeshfard Mohammad
Street address
Semnan University of Medical Sciences

City
Semnan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Raheb Ghorbany
Street address
Semnan University of Medical Sciences
City
semnan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
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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