

# 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

##### Name

Mohammad Forozeshfard

##### Name of organization / entity

Semnan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 2362 2990

##### Email address

mff@sem-ums.ac.ir

#### 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

**Name of organization / entity**  
Semnan University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
Professional MD  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### 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*