

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison of preventive effects of intrathecal pethidine and morphine on post spinal anesthesia shivering in patients undergoing elective cesarean section

#### Protocol summary

##### Summary

Preventive effects of intrathecal morphine versus intrathecal pethidine on shivering after spinal anesthesia in patients undergoing elective cesarean surgery, a randomized double-blind intervention study with a control group criteria: candidates for elective caesarean section. Fill the consent form to participate in the study Exclusion Criteria: contraindications to spinal anesthesia. states of emergency. target= prevent shivering size of sample = 90 time of intervention = 6 months

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013091414656N1**  
Registration date: **2013-10-15, 1392/07/23**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-10-15, 1392/07/23

##### Registrant information

###### Name

Erfan Khezripour

###### Name of organization / entity

Kurdistan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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##### Recruitment status

##### Recruitment complete

##### Funding source

Kurdistan University of Medical Sciences

##### Expected recruitment start date

2013-03-20, 1391/12/30

##### Expected recruitment end date

2013-09-21, 1392/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of preventive effects of intrathecal pethidine and morphine on post spinal anesthesia shivering in patients undergoing elective cesarean section

##### Public title

Influence of drugs pethidine and morphine in prevention of shivering after anesthesia in women undergoing cesarean section

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

The study population consisted of patients for elective cesarean section is referring to the operating room Besat Hospital in Sanandaj city. Inclusion criteria: - candidate for elective caesarean section - fill the consent form to participate in the study - physical status class I or II according to the American Society of Anesthesia Exclusion Criteria: - contraindications to spinal anesthesia - patients with valvular heart disease - pulmonary hypertension - diabetes - preeclampsia - eclampsia - Sepsis - Emergency situations - Lumbar Spine Disorders

##### 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)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Inclusion criteria for patients who have 60 patients in two groups of 30 each in a randomized block (Block 6 persons) are located. The 25% incidence of shivering in patients undergoing spinal anesthesia are, and taking into account the 80% of power. Alpha equal to 0.05 for a sample size of 28 patients per group was calculated to increase the accuracy of the results of 30 patients in each group (n = 60) was promoted.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Kurdistan University of Medical Sciences

**Street address**

, Opposite the hotel Shadi, Pasdaran avenue -

**City**

Sanandaj

**Postal code**

66177-13446

**Approval date**

2012-09-22, 1391/07/01

**Ethics committee reference number**

MUK.REC.1392.13

**Health conditions studied****1****Description of health condition studied**

Shivering after spinal anesthesia

**ICD-10 code**

074.6

**ICD-10 code description**

Other complications of spinal and epidural anaesthesia during labour and delivery

**Primary outcomes****1****Description**

Intensity of shivering after spinal anesthesia

**Timepoint**

After the intervention, the patient was awake in the recovery room to the exit from the operating room

**Method of measurement**

Evaluation standards for patient access time of discharge from chill out and chill duration and intensity based segmentation is based on 4 minutes scores is made Zero: no chills. Grade: mild fasciculation in the face and neck. Grade: trembling visible muscle groups in more than one category. Grade III: the major muscular activity involving the entire body.

**Secondary outcomes****1****Description**

Medication side effects (nausea, vomiting, nystagmus, hypotension requiring treatment, bradycardia requiring medication)

**Timepoint**

Immediately after the surgical intervention.

**Method of measurement**

based on observation of Anesthesiologists in the operating room and recovery room based on the observation of Anesthesia Technician

**Intervention groups****1****Description**

First, all persons entering the operating room for elective caesarean section in a registration form are numbered. Then, based on the criteria of inclusion and exclusion criteria of inclusion and exclusion criteria and if give informed consent to participate in research, are filed in Form No. 2. If you have exclusion criteria, number one, because it will be mentioned in the same form. Randomized and referred to by the same anesthetic technicians will perform their work and involvement in the assessment will not only prepare the drug. The participants will be divided into two groups of 30 patients by the statistical and methodological consultant to anesthesia technician. Essential drugs list based on a statistical consultant to the technicians, producers and labels on individual numbers are labeled. The drug is administered by an anesthesiologist. Group A and Group B pethidine to morphine 10 mg of 2/0 mg with 5/12 mg bupivacaine Hyprbar 5/0%, spinal needle is injected into the subarachnoid space, Site of needle insertion, number of attempts to find the subarachnoid space is recorded by an anesthesiologist then supine status of the patient has been injected fluid variables, spinal anesthetic is injected with the drug. Any complications during the surgery and recovery if it is

administered. Measurements will be performed by an anesthesiologist.

**Category**

Prevention

**2****Description**

The control group consisted of 30 people who are either on the same criteria entry and exit in the intervention group had been selected. The difference between the control group and the drug pethidine and morphine as the prevention of spinal anesthesia shivering are not used just the patient undergo spinal anesthesia by bupivacaine then all variables were recorded in the forum like intervention group.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Sanandaj- Besat hospital

**Full name of responsible person**

Erfan Khezripour

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plaque75-lane ansar7-kurdistan street-sanandaj

**City**

Sanandaj

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kurdistan University of Medical Sciences

**Full name of responsible person**

Dr. Ataollah Heidari

**Street address**

research office-kurdistan medical university-sanandaj

**City**

Sanandaj

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kurdistan 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**

Kurdistan University of Medical Sciences

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Erfan Khezripour

**Position**

Medical student

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**Web page address****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*