Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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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 05/0 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 madeZero: 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.Randvmyzyshn 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

Street address

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

Full name of responsible person

Erfan Khezripour

Position

Medical student

Other areas of specialty/work

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Person responsible for updating data

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Position

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Other areas of specialty/work

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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