Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of intrathecal injection of pethidine, pethidine-bupivacaine and bupivacaine on pain severity and hemodynamic parameters after elective cesarean section

Protocol summary

Study aim

The aim of this study is to compare postoperative analgesia, hemodynamics and Apgar score of neonates in cesarean section patients under spinal anesthesia with pethidine, bupivacaine, and a combination of the two.

Design

In this double-blind randomized clinical trial, the rate of postoperative analgesia in 90 healthy women candidates for elective cesarean section with spinal anesthesia using pethidine, bupivacaine, and a combination of these two drugs will be evaluated. The method of data collection is using a questionnaire. Patients will be divided into 3 groups (30 patients in each).

Settings and conduct

In this double-blind clinical trial that will be performed in Vali Asr Hospital in Birjand, the rate of postoperative analgesia in healthy patients who are candidates for elective cesarean section with spinal anesthesia using pethidine, bupivacaine and a combination of these two drugs will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ASA 1 and ASA 2 from 20 to 40 years; No drug and smoking addiction; No history of hypertension, diabetes, and uncontrolled comorbidities; Elective cesarean section; No chronic pain; No mental disorder and hysteria Exclusion criteria: Emergency cesarean section; Placental abruption; Placental accreta; Severe bleeding during surgery; Drug and smoking addiction; Uncontrolled comorbidities; Take painkillers or antiemetics 24 hours before surgery; Skin infection at the site of lumbar injection; Bupivacaine or pethidine allergy history; Intraoperative change of anesthesia type; Intraoperative Blood transfusion

Intervention groups

Healthy pregnant women aged 20 to 40 years undergo spinal anesthesia in three groups (one group with pethidine, the other group with bupivacaine and the last group with pethidine-bupivacaine mixture).

Main outcome variables

SBP DBP HR Apgar score Need for painkiller PONV Age Itching Shortness of breath

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200413047056N2**
Registration date: **2021-01-28, 1399/11/09**
Registration timing: **prospective**

Last update: **2021-01-28, 1399/11/09**
Update count: **0**

Registration date

2021-01-28, 1399/11/09

Registrant information

Name

malihe zangoue

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-31, 1399/11/12

Expected recruitment end date

2021-04-01, 1400/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of intrathecal injection of pethidine, pethidine-bupivacaine and bupivacaine on pain severity and hemodynamic parameters after elective cesarean section

Public title

Comparison of pethidine and bupivacaine in spinal anesthesia

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

ASA 1 and ASA 2 (patients with healthy or controlled mild disease) in the range of 20 to 40 years No drug and smoking addiction No history of hypertension, diabetes and uncontrolled comorbidities Elective cesarean section No chronic pain No mental disorder and hysteria

Exclusion criteria:

Emergency cesarean section Placental abruption Placental accreta Severe bleeding during surgery Drug and smoking addiction Uncontrolled comorbidities Take painkillers or antiemetics 24 hours before operation Skin infection at the site of lumbar injection History of bupivacaine or pethidine allergy Change ofanesthesia type during the operation Blood transfusion during the operation

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

1-2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, a simple randomization method will be used. In this way 90 sealed envelopes, each containing a card of a different color and each color representing a group, will be placed in a box. After entering the operating room, if the patient has the inclusion criteria, she will pull one envelope out of the box and will be placed in the desired group according to the color of the card inside.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind clinical study, 90 sealed envelopes, each containing a card of a different color and each color representing a group, will be placed in a box. After entering the operating room, if the patient has the inclusion criteria, she will pull one envelope out of the box and will be placed in the desired group according to the color of the card inside, and then the drug will be prepared by an independent researcher (anesthesia technician).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical Sciences

Street address

Ghaffari Ave

City

Birjand

Province

South Khorasan

Postal code

۹۷۱۷۸۵۳۵۷۷

Approval date

2019-07-23, 1398/05/01

Ethics committee reference number

IR.BUMS.REC.1398.144

Health conditions studied

1

Description of health condition studied

The rate of analgesia in cesarean section

ICD-10 code

O74.6

ICD-10 code description

Other complications of spinal and epidural anesthesia during labor and delivery

Primary outcomes

1

Description

pain

Timepoint

Within 24 hours after the intervention

Method of measurement

Number of suppositories consumed

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Healthy pregnant women 20 to 40 years old undergoing spinal anesthesia with pethidine. After prepping and draping, spinal anesthesia with 100mg of pethidine will be performed using a 25 G Quincke needle in the L4-L5 or L5-S1 intervertebral space in a sitting position. After the injection, the patient is immediately returned to the supine position, and standard monitoring including continuous pulse oximetry and ECG will be used.
Category
Treatment - Drugs

2

Description
Intervention group 2: Healthy pregnant women 20 to 40 years old undergoing spinal anesthesia with bupivacaine. After prepping and draping, spinal anesthesia with 10mg of bupivacaine will be performed using a 25 G Quincke needle in the L4-L5 or L5-S1 intervertebral space in a sitting position. After the injection, the patient is immediately returned to the supine position, and standard monitoring including continuous pulse oximetry and ECG will be used.
Category
Treatment - Drugs

3

Description
Intervention group 3: Healthy pregnant women 20 to 40 years old undergoing spinal anesthesia with the pethidine-bupivacaine mixture. After prepping and draping, spinal anesthesia with 50mg of pethidine and 5mg of bupivacaine will be performed using a 25 G Quincke needle in the L4-L5 or L5-S1 intervertebral space in a sitting position. After the injection, the patient is immediately returned to the supine position, and standard monitoring including continuous pulse oximetry and ECG will be used.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali Asr Hospital, Birjand
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
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Maliheh Zangoue
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Consultant
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Total data after unidentifiable individuals
When the data will become available and for how long
One year after the results are published
To whom data/document is available
every one
Under which criteria data/document could be used
For research
From where data/document is obtainable
By Email with corresponding
What processes are involved for a request to access data/document
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