Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

Determination and comparison of the effects of intraperitoneal bupivacaine, morphine and dexamethasone on postoperative pain in women 20 to 45 years old undergoing elective cesarean section with general anesthesia

Protocol summary

Summary

The aim of this study is to determine and compare the effects of intraperitoneal administration of bupivacaine, morphine and dexamethasone on post cesarean section pain control. This is an interventional, single-center, controlled with placebo and randomized study on 144 pregnant women 20 to 45 years old with American Society of Anesthesia(ASA) class I and II, who candidate for elective cesarean section. Emergency cases, individuals with history of opioid addiction, and chronic pain syndrome were excluded. This study is double-blinded. Anesthesiology resident and patients do not inform about kinds of drugs. Patients were randomly divided into four groups (n= 36) on the basis of selection of colored cards. All patients underwent General anesthesia with similar method. At the end of surgery in group one 30 cc of bupivacaine 0.025% and in group two 16 mg of dexamethasone that was diluted to 30 cc and in group three 5mg of morphine that was diluted to 30 cc and in control group 30 cc of saline was poured intraperitonealy by the surgeon. Postoperative pain was recorded with the use of a visual analog scale with scores ranging from 1 to 10 at 2, 4 and 6 h intervals after the surgery. Analgesia requirements, vital signs (blood pressure and heart rate) and incidence of nausea and vomiting were also recorded. Additional analgesics (intravenous meperidine 0.5 mg / kg) was administered to the patients with visual analog scale more than 3 in the postoperative period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602167695N7**

Registration date: **2016-03-13, 1394/12/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-13, 1394/12/23

Registrant information

Name

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Name of organization / entity

Qazvin University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Qazvin University of Medical Sciences

Expected recruitment start date

2015-01-01, 1393/10/11

Expected recruitment end date

2015-08-21, 1394/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination and comparison of the effects of

intraperitoneal bupivacaine, morphine and dexamethasone on postoperative pain in women 20 to 45 years old undergoing elective cesarean section with general anesthesia

Public title
Determination and comparison the effects of intraabdominal pouring of bupivacaine, morphine and dexamethasone on postoperative pain after cesarean section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Elective cesarean surgery; ASA class 1 and 2; first or second cesarean section; patients aged 20 to 45 years; the weight of the patient in the range of 60 to 90 kg. Exclusion criteria: The reluctance of patients; emergency cases; hypersensitivity to bupivacaine; dexamethasone and morphine; Patients with chronic pain syndrome and chronic Undertreatment with Nonsteroidal anti-inflammatory drugs; opium addiction.
Age
From **20 years** old to **45 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **144**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Other
Other design features
This study is double-blinded. Anesthesiology resident and patients do not inform about kinds of drugs. Random sampling is based on selection of colorful carts by patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Qazvin University of Medical Sciences
Street address
Qazvin University of Medical Sciences, Shahid Bahonar avenue, Qazvin
City
Qazvin
Postal code
3419759811
Approval date
2015-01-10, 1393/10/20
Ethics committee reference number
9883/20/د

Health conditions studied

1

Description of health condition studied
Pain after cesarian section
ICD-10 code
094-099
ICD-10 code description
Other obstetric conditions, not elsewhere classified

Primary outcomes

1

Description
The severity of pain
Timepoint
Every 2 hours till 6 hours after cesarean section
Method of measurement
Score of Pain according to visual analog scale

2

Description
Amount of analgesic consumption
Timepoint
Every 2 hours till 6 hours after cesarean section
Method of measurement
Total dose of administered meperidine (mg)

Secondary outcomes

1

Description
Heart rate
Timepoint
Every 2 hours till 6 hours after cesarean section
Method of measurement
Counting heart rate in1 minute

2

Description
Blood pressure
Timepoint
Every 2 hours till 6 hours after cesarean section
Method of measurement
Sphygmomanometer

3

Description
Nausea and vomiting
Timepoint
Every 2 hours till 6 hours after cesarean section
Method of measurement
2 points scale: 1: nausea and vomiting , 2: non

Intervention groups

1

Description
At the end of surgery, in the group one, 30 cc of bupivacaine 0.025% was poured into the peritoneum by the surgeon.
Category
Prevention

2

Description
At the end of surgery, in the group two, 16 mg of dexamethasone that was diluted to 30 cc with saline was poured into the peritoneum by the surgeon.
Category
Prevention

3

Description
At the end of surgery, in the group three, 5mg of morphine that was diluted to 30 cc with saline was poured into the peritoneum by the surgeon.
Category
Prevention

4

Description
At the end of surgery, in the control group, 30 cc of saline was poured into the peritoneum by the surgeon.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Koosar hospital
Full name of responsible person
Tahere Mahmoody
Street address
Valiasr street, Qazvin.
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Qazvin University of Medical Sciences
Full name of responsible person
Dr. Taghi Naserpour Farivar
Street address
Qazvin University of Medical Sciences, Shahid Bahonar avenue, Qazvin.
City
Qazvin
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Qazvin 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
Koosar hospital
Full name of responsible person
Tahere Mahmoody
Position
Anesthesiology Resident
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Koosar hospital
Full name of responsible person

Masoumeh Hosseini Valami

Position

Associate Professor of Anesthesiology

Other areas of specialty/work

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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