

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 intraperitoneally 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

Seyedeh Masoumeh Hosseini Valami

Name of organization / entity

Qazvin University Of Medical Sciences

Country

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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
9883/20/3

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 in 1 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

Other areas of specialty/work

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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