Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of effect of site of catheter for bupivacain administration in midline laparotomy on postoperative pain in Shariati hospital patients in 2011-2012

Protocol summary

Summary

The objective of this randomized controlled trial is to compare the effect of site of administration of Bupivacain with catheter into the midline laparotomy wound on postoperative pain (Over or between fascia). Informed consent is taken before enrollment in the study. A total of 60 patients with midline laparotomy (20-30 cm incision) are randomly assigned into one of the two groups: "Catheter on the fascia" and "Catheter between layers of rectus muscle". 20 cc of bupivacain 0.25% are administered via each catheter every 6 hours for 48 hours. The pain is assessed by visual analogue score each 12 hours by a blinded observer. Analgesia by narcotics are administered by patient-controlled analgesia system (bolus dose = 1mg morphine sulphate with 8 min lock-out time) and the need for narcotics are compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810142982N1**
Registration date: **2011-11-04, 1390/08/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-11-04, 1390/08/13

Registrant information

Name

Zhamak Khorgami

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-02-20, 1390/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of site of catheter for bupivacain administration in midline laparotomy on postoperative pain in Shariati hospital patients in 2011-2012

Public title

Effect of site of catheter for bupivacain administration in laparotomy wound on postoperative pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients undergoing midline laparotomy for elective surgeries and sign informed consent for participating in the study Exclusion Criteria: substance abuse, no appropriate verbal communication, simultaneous other incisions, critically ill or unstable patients, being unconscious or intubated in postoperative period

Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Central building of Tehran University of Medical Science, Ghods Avenu, Keshavarz Blvd
City
Tehran
Postal code
Approval date
2008-04-18, 1387/01/30
Ethics committee reference number
6688

Health conditions studied

1

Description of health condition studied
Pain management after laparotomy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Total postoperative narcotic consumption
Timepoint
Untill 72 hours based on PCA device
Method of measurement
Patient controlled analgesia device

Secondary outcomes

1

Description
postoperative nausea and vomitting
Timepoint
daily till 48 hours after surgery
Method of measurement
History taking and clinical records

2

Description
postoperative Cardiavascular complications
Timepoint
daily till 48 hours after surgery
Method of measurement
based on medical reocords

3

Description
postoperative pulmonary complications
Timepoint
daily till 48 hours after surgery
Method of measurement
based on medical reocords

4

Description
Wound infection
Timepoint
daily till 5 days after surgery
Method of measurement
Physical examination

5

Description
Hospital stay
Timepoint
At the time of discharge
Method of measurement
based on medical reocords

6

Description
Postoperative pain
Timepoint
12 hours intervals for 3 days
Method of measurement
Visual analogue scale

Intervention groups

1

Description
In group "Catheter between fascia", two infant feeding tubes (6 Fr) - with added holes - are place between rectus muscle and posterior fascia. 20 cc of bupivacain 0.25% are administered via each catheter every 6 hours for 48 hours. The pain is assessed by visual analogue score each 12 hour by a blinded observer. Analgesia by narcotics are used by patient-controlled analgesia system and the need for narcotics are being compared.

Category
Treatment - Surgery

2

Description
In group "Catheter on the fascia", after fascia closure, two infant feeding tubes (6 Fr) - with added holes - are placed over the fascia in subcutaneous space. 20 cc of bupivacain 0.25% are administered via each catheter every 6 hours for 48 hours. The pain was assessed by visual analogue score each 12 hour by a blinded observer. Analgesia by narcotics are used by patient-controlled analgesia system and the need for narcotics are being compared.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati Hospital

Full name of responsible person
Zhamak Khorgami

Street address
Shariati Hospital, North Kargar Avenue,

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Shahin Akhonzade

Street address
Research deputy, Medicine faculty, Poursina avenue, Keshavarz Blvd

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran 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
Tehran University of Medical Sciences - Shariati Hospital

Full name of responsible person
Zhamak Khorgami

Position
General Surgeon / faculty of surgery department

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Web page address

Person responsible for updating data

Contact

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