

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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)

Phone

+98 21 8490 2450

Email address

khorgami@tums.ac.ir

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 placed 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

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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

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 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