

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effect of intercostal nerve block added infusion of intravenous morphine versus infusion of intravenous morphine only for pain control after open cholecystectomy

Protocol summary

Summary

The aim of this study is to compare the efficacy of intercostal nerve block added intravenous infusion of morphine with intravenous morphine for pain control after open cholecystectomy. In 100 patients who are candidate for open cholecystectomy randomized divided in two 50 groups. The patients underwent elective cholecystectomy were randomly allocated to any of the following two groups comprising of 50 patients each group. Group intervention was allocated for intercostal nerve block with 0.25 milligrams per kilogram of bupivacaine diluted in 2.5 milligrams per milliliter was infiltrated in the subcostal 6 to 10 rib margin then intravenous Patient-controlled analgesia with 0.5 milligrams per kilogram morphine started. In control Group patients had intravenous Patient-controlled analgesia with only 0.5 milligrams per kilogram morphine. The infusion rate is 5 milliliters per hour. When the patients shifted to postoperative recovery room where intensity of pain was recorded by response from the patients using 100 mm linear visual analogue scale (VAS) ranging from 0 to 100. The pain scoring was done at 30 minutes, 6 hours, 12 hours, 18 hours and 24 hours postoperatively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120320112N2**

Registration date: **2014-12-15, 1393/09/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-15, 1393/09/24

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Birjand University Of Medical Sciences

Expected recruitment start date

2009-04-23, 1388/02/03

Expected recruitment end date

2013-03-21, 1392/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of intercostal nerve block added infusion of intravenous morphine versus infusion of intravenous morphine only for pain control after open cholecystectomy

Public title

Effect of intercostal nerve block on the pain after open cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: American society of anesthesiologist
class 1 and 2; age 20-60 year exclusion criteria:
addiction to opium and sedative drugs; epilepsy

Age

From **27 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Birjand University of Medical Sciences

Street address

N:56, Ghafari Ave.

City

Birjand

Postal code

1973456783421589

Approval date

2009-04-23, 1388/02/03

Ethics committee reference number

5_2_1388

Health conditions studied

1

Description of health condition studied

Calculus of bile duct without cholangitis or cholecystitis

ICD-10 code

K80.5

ICD-10 code description

Calculus of bile duct without cholangitis or cholecystitis

Primary outcomes

1

Description

pain

Timepoint

in 30th minute and every 6 hours

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

in control group intercostal nerve block with 0.25 milligrams per kilogram bupivacaine diluted to 2.5 milligrams per milliliter injected in 6th to 10th subcostal margin and then the infusion of intravenous morphine 0.5 milligrams per kilogram start at infusion rate 5 milliliters per hour.

Category

Treatment - Drugs

2

Description

infusion of intravenous morphine 0.5 milligrams per kilogram start at infusion rate 5 milliliters per hour

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Pooya Derakhshan

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Imam Reza Hospital, Taleghani St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Hasan Karbasi

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Ghafari Ave.

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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
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

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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