Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

the effect of intraperitoneal lidocaineand bupivacain on post operative pain in laparoscopic cholecystectomy compare with normal saline in patient who are undergoing laparoscopic cholecystectomy .

Protocol summary

Summary

Laparoscopic cholecystectomy is the treatment of choice for symptomatic cholelithiasis, laparoscopic cholecystectomy result in less post-operative pain compared with open cholecystectomy, post-operative pain after laparoscopic cholecystectomy remain an issue ,pain can prolong hospital stay and lead to increased morbidity; the type of pain after laparoscopy differs from that observed after laparotomy, patients complain more of visceral pain after laparoscopy. Shoulder pain secondary to diaphragmatic as a result if CO2 pneumoperitoneum after laparoscopy surgery. Pain after laparoscopy may be moderate or even severe for some patients and may require opioid treatment. Although opioid have played a prominent role in reduce of post-operative pain, but the side effect such as ilius and vomiting and nausea may limit their future use in some patients. Several authors have reported a substantial decrease in post-operative pain after laparoscopic cholecystectomy with the use of intra peritoneal local anesthesia. The aim of this study is to compare the lidocaine and bupivacain with normal saline on reduce pain and vomiting and nausea after cholecystectomy laparoscopic. Material and methods: A total of 168 patients undergoing laparascopic cholecystectomy were randomly assigned to three groups (Group A, Group B, and Group C). On the completion of cholecystectomy, 20 mL of lidocaine 1% was infused intraperitoneally in Group B, 20 mL of Bupivacain 0.25% was infused intraperitoneal in Group C, and 20 mL of normal saline was infused intraperitoneally in Group A. The incidence and severity of PONV, the pain score, and the rescue analgesics were assessed 0 min, 15 min, 30 min, 1 h, 2 h, 6 h, 12 h, and 24 h after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014020716516N1**
Registration date: **2014-08-12, 1393/05/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-08-12, 1393/05/21

Registrant information

Name

Sadeghe Nadri

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 3322 3004

Email address

dr.s.nadri@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Lorestan University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
the effect of intraperitoneal lidocaineand bupivacain on post operative pain in laparoscopic cholecystectomy compare with normal saline in patient who are undergoing laparoscopic cholecystectomy .

Public title
the effect of intraperitoneal lidocaineand bupivacain on post operative pain in laparoscopic cholecystectomy compare with normal saline in patient who are undergoing laparoscopic cholecystectomy .

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients that are candidate foe elective laparoscopic cholecystectomy; age between 20-70 years old. Exclusion criteria: the patients that have heart disease and hypertension and diabetes mellitus and chronic respiratory diseases.

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **168**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
khoramabad medicein university

Street address
khoramabad kilometer30 road khoramabad-boroujerd

City
khoramabad

Postal code
www.lums.ac.ir

Approval date
2012-10-27, 1391/08/06

Ethics committee reference number
200,76316

Health conditions studied

1

Description of health condition studied
Chronic cholecystitis

ICD-10 code
K81.1

ICD-10 code description
Chronic cholecystitis

Primary outcomes

1

Description
Pain

Timepoint
24 hours after surgery

Method of measurement
VAS score system

Secondary outcomes

1

Description
Nausea and vomiting

Timepoint
Questionnaire

Method of measurement
24 hours after surgery

2

Description
Blood pressure

Timepoint
Blood pressure measuring device

Method of measurement
24 hours after surgery

3

Description
Pulse rate

Timepoint
24 hours after surgery

Method of measurement
Pulse oximertry

Intervention groups

1

Description
20 mL of lidocaine 1% was infused , and 20 mL of normal saline was infused intraperitoneally in Group A.

Category
Treatment - Drugs

2

Description
20 mL of lidocaine 1% was infused intraperitoneally in Group B,
Category
Treatment - Drugs

3

Description
20 mL of Bupivacain 0.25% was infused intraperitoneally in Group C
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Ashyer hospital
Full name of responsible person
dr. Ssedighe Nadri
Street address
Enghelab street
City
Khoramabad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Lorestan University of Medical Sciences
Full name of responsible person
Dr. Sedigheh Nadri
Street address
3 kilometer road khoramabad-boroujerd
City
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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
Lorestan 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
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Full name of responsible person
Dr. Sedigheh Nadri
Position
Physician Anesthesiologist
Other areas of specialty/work
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Person responsible for updating data

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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