Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Intraoperative Intravenous lidocaine infusion And comparison with the effect of intravenous remifentanil infusion , on postoperative pain after laparoscopic cholecystectomy surgery

Protocol summary

Study aim

Effect of Intraoperative Intravenous lidocaine infusion And comparison with the effect of intravenous remifentanil infusion , on postoperative pain after laparoscopic cholecystectomy surgery

Design

Double Blinded Randomized Clinical Trial

Settings and conduct

In this study, that performed in the operating room of Shahid Faghihi Hospital in Shiraz, 81 patients undergoing laparoscopic cholecystectomy were divided into three groups.Patients in group(A) received 2% lidocaine (1.5 mg / kg) immediately after endotracheal intubation.Then the 2% lidocaine infusion at 2 mg / kg will start for 15 to 20 minutes before the skin closes. Patients in intervention group 2(B) received Remifentanil infusion 0.5 µg / kg / min and continued until 15-20 minutes before the skin closure and patients . In intervention group 3(C) patients received normal Saline infusion 0.9% for 20 to 15 minutes before skin closure.

Participants/Inclusion and exclusion criteria

Inclusion Criteria:ASA I-اوl Age 18 to 75 yearsو Patients Candidate for Laparoscopic Cholecystectomy Exclusion Criteria: A history of allergies to topical anesthetics and lidocaine and opioids, Chronic use of opioids and nonsteroidal anti-inflammatory drug and alcohol, Pregnancy, History of (heart, liver and kidney) failure , Heart rate less than 50 minutes per minute, any block on the ECG

Intervention groups

Patients in group(A) received 2% lidocaine (1.5 mg / kg) immediately after endotracheal intubation.Then the 2% lidocaine infusion at 2 mg / kg will start for 15 to 20 minutes before the skin closes. Patients in intervention group 2(B) received Remifentanil infusion 0.5 µg / kg / min and continued until 15-20 minutes before the skin closure and patients . In intervention group 3(C) patients received normal Saline infusion 0.9% for 20 to 15 minutes before skin closure.

Main outcome variables

Postoperative pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N89**
Registration date: **2019-10-18, 1398/07/26**
Registration timing: **prospective**

Last update: **2019-10-18, 1398/07/26**
Update count: **0**

Registration date

2019-10-18, 1398/07/26

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3647 4270

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masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-06, 1398/08/15

Expected recruitment end date

2020-02-04, 1398/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Intraoperative Intravenous lidocaine infusion And comparison with the effect of intravenous remifentanil infusion , on postoperative pain after laparoscopic cholecystectomy surgery

Public title

Effect of Intraoperative Intravenous lidocaine infusion And comparison with the effect of intravenous remifentanil infusion , on postoperative pain after laparoscopic cholecystectomy surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

ASA I-II Age 18 to 75 years Patients Candidate for Laparoscopic Cholecystectomy

Exclusion criteria:

Non-cooperation patients after surgery Severe physical and mental disorders Severe bradycardia (heart rate less than 40 times per minute) Severe bleeding leading to laparotomy A history of allergies to topical anesthetics and lidocaine and opioids Chronic use of opioids and nonsteroidal anti-inflammatory drug and alcohol Pregnancy History of heart, liver and kidney failure The heart rate is less than 50 minutes per minute and any block on the ECG

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **81**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into lidocaine (A), remifentanil (B) or normal saline (C) injection groups using computer-assigned codes which is derived from Randomization.org.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are divided into lidocaine (A), remifentanil (B) or normal saline (C) injection groups using computer-assigned codes. Then an anesthetist unaware of study groups adminestered the drugs according to computer-selected codes syringes (containing lidocaine A) for patients with code (A) and syringe (containing normal saline C) for patients with code (C) and syringe B contains remifentanil for patients with code (B). A nurse who is blinded to the study collects information. Bolus medications are given in a 5-cc syringe and infusions in a 50-cc syringe are given by the anesthetic nurse.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2019-04-16, 1398/01/27

Ethics committee reference number

SUMS.MED.REC.1398.46

Health conditions studied

1

Description of health condition studied

Acute cholecystitis

ICD-10 code

K80.0

ICD-10 code description

Calculus of gallbladder with acute cholecystitis

Primary outcomes

1

Description

Severity of pain in recovery

Timepoint

On arrival to recovery and every 15 minutes to 60 minutes in recovery

Method of measurement

NRS

2

Description
Severity of pain in the ward
Timepoint
Every one hour up to 6 hours, and then 12 and 24 hours
Method of measurement
NRS

Secondary outcomes

1

Description
Sedation Score
Timepoint
At the arrival to the recovery room
Method of measurement
four-point categorical scale

Intervention groups

1

Description
Intervention group: Immediately after endotracheal intubation, lidocaine 2% solution (1.5 mg / kg) will be administered slowly. Then lidocaine 2% infusion at 2 mg / kg dose will start with syringe pump infusion. and 15 to 20 minutes before closing the skin continues.
Category
Prevention

2

Description
Intervention group: Remifentanil infusion at a dose of 0.5 µg / kg / min is used and lasts up to 15-20 minutes before completion of skin closure.
Category
Prevention

3

Description
Control group: The infusion of 0.9% normal saline solution continues until 20-20 minutes before the skin closure.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital
Full name of responsible person
Amir Javadi
Street address
Shahid Faghihi Hospital, Zand Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Younes Ghasemi
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Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand
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vcrdep@sums.ac
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Amir Javadi
Position
Anesthesiology Resident
Latest degree

Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available