

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-III, Age 18 to 75 years, 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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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
remifentanyl infusion , on postoperative pain after
laparoscopic cholecystectomy surgery

Public title
Effect of Intraoperative Intravenous lidocaine infusion
And comparison with the effect of intravenous
remifentanyl 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), remifentanyl (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), remifentanyl (B) or
normal saline (C) injection groups using computer-
assigned codes. Then an anesthetist unaware of study
groups administered 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 remifentanyl 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

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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

Street address

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

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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

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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Latest degree

Specialist

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)

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