Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the effectiveness of intraoperative infusion of lidocaine on postoperative pain in laparoscopic cholecystectomy.

Protocol summary

Summary

The main goal of this study is determining the effectiveness of intraoperative infusion of lidocaine on postoperative pain in laparoscopic cholecystectomy. This is a randomized clinical trial on 70 patients which are divided in two groups randomly using chances box. Inclusion criteria are patient willingness to participation, ASA (American Society of Anesthesiologists) classification of I or II and elective laparoscopy. Exclusion criteria are history of sensitivity to local analgesics, long-lasting use of narcotics and steroids, pregnancy and history of cardiac or other chronic diseases. The method of anesthesia in both groups is identical. In first group 1.5 mg/kg lidocaine is administrated 10 minutes before anesthesia and maintenance dose of 2mg/kg/hr is given by infusion pump until the end of operation. In second group we administer placebo but induction medication and maintenance of anesthesia is similar to the first group. Blood pressure and heart rate of all is measured before induction, after beginning of surgery, at the time of starting CO2 course, and every 15 minutes throughout the procedure till the end of recovery period. The patients' pain is measured before anesthesia and after the procedure in recovery room using Visual Analogue Scale (VAS). In order to preventing analgesics' effects on VAS, 30 minutes before the end of surgery administration of fentanyl (an analgesic) is stopped up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013082110900N2**
Registration date: **2013-09-22, 1392/06/31**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-09-22, 1392/06/31

Registrant information

Name
Hosein Sattari
Name of organization / entity
kerman University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 34 1322 2250
Email address
sattari@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research, Kerman University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of intraoperative infusion of lidocaine on postoperative pain in laparoscopic cholecystectomy.

Public title

Can lidocaine infusion during laparoscopic surgery reduce the pain?

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria are patient willingness to participation, ASA (American Society of Anesthesiologists) classification of I or II and elective laparoscopy. Exclusion criteria are history of sensitivity to local analgesics, long-lasting use of narcotics and steroids, pregnancy and history of cardiac or other chronic diseases and high blood pressure, age less than18 or more than 85, BMI more than 40, HR less than 50 and PR interval more than 0.2 sec. or any kind of cardiac block.
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
After approving by Ethic Committee of Kerman University of Medical Sciences, informed consent will be obtained from the patients. The method of sampling is simple randomization which amongst studied members of community who are referred to operation rooms of Afzalipoor Hospital of kerman, one sample will be selected from the listed groups in the chances box by the patient accidentally. The medication is prepared by study leader and the anesthesiologist and technician who are responsible for taking care of the patient are blind to the medication as well as the patient. The preparation of patients in both group are similar and all the patients must be NPO for 8 hours before operation.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical sciences
Street address
Jomhoori boulevard
City
Kerman
Postal code
Approval date
2013-09-21, 1392/06/30
Ethics committee reference number
k/92/223

Health conditions studied

1

Description of health condition studied
Cholecystectomy
ICD-10 code
K81
ICD-10 code description
Cholecystitis

Primary outcomes

1

Description
pain
Timepoint
before and after operation
Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

1

Description
blood pressure
Timepoint
every 5 minutes and every 15 minutes in PACU
Method of measurement
digital monitoring device

2

Description
Heart Rate
Timepoint
every 5 minutes and every 15 minutes in PACU
Method of measurement
digital monitoring device

Intervention groups

1

Description
In intervention group Lidocaine (each ampoule contains 20 mg/ml Lidocaine, made by Daroopakhsh Co - Iran) with primary dose of 0.5 mg/kg and maintenance dose of 2 mg/kg/h is administered.
Category
Treatment - Drugs

2

Description
In control group placebo (normal saline) is administered.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipoor Hospital
Full name of responsible person
Maryam Etminan
Street address
Afzalipoor Hospital
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Hassani
Street address
Tahmasbabad Square, Ebnesina Street
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Hssein Sattari
Position
Anesthesiologist
Other areas of specialty/work
Street address
Afzalipoor Hospital
City
Kerman
Postal code
Phone
+98 34 1322 2250
Fax
Email
hosattari@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Maryam Etminan
Position
resident of anesthesia
Other areas of specialty/work
Street address
Afzalipoor Hospital
City
Kerman
Postal code
Phone
+98 34 1322 2250
Fax
Email
javakrd34@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Maryam Etminan
Position
Resident of anesthesia
Other areas of specialty/work
Street address
Afzalipoor Hospital
City
Kerman
Postal code
Phone
+98 34 1322 2250
Fax
Email
Web page address

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