

# 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 than 18 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 Daroopaksh 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

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#### 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

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##### 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*