Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of analgesic effects of intravenous infusion of Lidocaine and Ketamine during surgery on acute pain after elective laparotomy surgery.

Protocol summary

Summary

(1) Objectives: the purpose of this study is evaluation of analgesic effects of intravenous infusion of Lidocaine and Ketamine during surgery on acute pain after elective laparotomy surgery. (2) Design: this study is a double-blind randomized controlled trial and will be accomplished in Hazrat-e-rasool akram hospital in Tehran, Iran between 2013 and 2014. This trial is a phase III study. The participants are 80 patients, both male and female.The patients will be divided in two groups based on random number table. In one group Lidocaine and Ketamine will be infused during surgery and in the other group general anesthesia will just be induced. (3) Setting and conduct: in one group after induction of general anesthesia, intravenous Lidocaine and Ketamine will be infused during surgery with assigned doses. In the other group general anesthesia will just be induced. (4) Inclusion criteria: ASA I, ASA II, Hb>10, age between 20 and 60. Exclusion criteria: hemodynamic instability, uncontrolled underlying disease, drug sensitivity, addiction to alcohol and opioids. (5) Intervention: in one group, 30 minutes after induction of general anesthesia, both drugs Lidocaine and Ketamine will be infused intravenously with the dose of 0.5 mg/kg/hr until termination of surgery. In the other group these drugs will not be infused and general anesthesia will just be induced. (6) Main outcome measures: for evaluation of efficacy of intervention on rate of pain, visual analogue scale (VAS) will be used. Side effects including cardiac arrhythmia, seizure, halucination, delirium, and drug sensitivity will be evaluated in patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071935187N1**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name

Alireza Bagheri

Name of organization / entity

Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of analgesic effects of intravenous infusion of Lidocaine and Ketamine during surgery on acute pain after elective laparotomy surgery.

Public title
Comparison of analgesic effects of intravenous infusion of Lidocaine and Ketamine on acute pain after elective laparotomy surgery in patients of two groups of purpose and control
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: ASA I, ASA II, Hb>10, elective laparotomy surgery, consent to participation, no important underlying disease. Exclusion criteria: uncontrolled underlying disease, addiction to alcohol and opioids, sensitivity to opioids, Ketamine or Lidocaine, weight>115kg, height<140cm.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
ندارد
Secondary trial Id
ندارد
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Near Milad tower, Shahid Hemmat Hwy.
City
Tehran
Postal code
1449614535
Approval date
2014-09-14, 1393/06/23
Ethics committee reference number
105/2891/93/د

Health conditions studied

1

Description of health condition studied
Acute pain after elective laparotomy surgery
ICD-10 code
G89.18
ICD-10 code description
Other acute post-procedural pain

Primary outcomes

1

Description
Comparison of acute pain after elective laparotomy surgery
Timepoint
Just after surgery, 6 hrs after surgery, 12 hrs after surgery, 18 hrs after surgery, 24 hrs after surgery
Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Seizure
Timepoint
Any time after beginning of signs & symptoms
Method of measurement
Patient and support person's complaint

2

Description
Cardiac arrhythmia
Timepoint
Any time after beginning of signs & symptoms
Method of measurement
Patient and support person's complaint and ECG

3

Description
Halucination
Timepoint
Any time after beginning of signs & symptoms
Method of measurement
Patient and support person's complaint

4

Description

Nausea & Vomiting

Timepoint

Any time after beginning of signs & symptoms

Method of measurement

Patient and support person's complaint

5

Description

Delirium

Timepoint

Any time after beggining of signs and symptoms

Method of measurement

Patient and support person's complaint

6

Description

Drug sensitivity

Timepoint

Any time after beginning of signs & symptoms

Method of measurement

Patient and support person's complaint

Intervention groups

1

Description

In the intervention group, 30 minutes after beginning of surgery, both drugs of Lidocaine and Ketamine will be infused intravenously for patients with the dose of 0.5 mg/kg/hr till end of surgery.

Category

Treatment - Drugs

2

Description

In the control group Lidocaine and Ketamine will not be infused for patients and general anesthesia will just be induced

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram hospital

Full name of responsible person

Dr. Farnad Imani, full profesor of anesthesiology

Street address

Rasool Akram hospital, Niyayesh Ave, Sattarkhan Blvd

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr. Alijavad Musavi

Street address

Iran University of Medical Sciences, Near Milad tower, Shahid Hemmat Hwy

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Iran 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

Iran University of Medical Sciences

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Dr. Farnad Imani

Position

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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