

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison the effect of intraoperative ketamine and systemic lidocaine on post operative pain management of opioid dependent patients undergoing orthopedic surgeries

Protocol summary

Summary

Acute postoperative pain control in opioid dependent patients is a challenging because of the unpredictability in achieving a satisfactory response to any given dose of opioid. In this randomized clinical trial 144 opioid dependent patients aging 20-50 years who will be candidate for orthopedic bone surgery under general anesthesia, will be randomly allocated to one of the three parallel groups In the group A, after induction of anesthesia, lidocaine will be started with a bolus 1.5 mg/kg followed by infusion 2 mg/kg per hour up to the end of the surgery and in the group B, Ketamine will be administered as a 0.5mg/kg bolus, followed by an infusion of 0.2 mg/kg per hour up to end of surgery. In the group C, normal saline will be started as a bolus, followed by an infusion up to end of surgery. Postoperative analgesia, sedation score, postoperative nausea and vomiting, patients satisfaction and respiratory depression will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070211662N10**
Registration date: **2016-09-09, 1395/06/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-09, 1395/06/19

Registrant information

Name

Mohammad Ali Sahmeddini

Name of organization / entity

Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences .

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of intraoperative ketamine and systemic lidocaine on post operative pain management of opioid dependent patients undergoing orthopedic surgeries

Public title

Comparison the effect of the intravenous ketamine versus lidocaine in decreasing severity of pain in opioid addicted patients undergoing orthopedic surgeries.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The eligible participants were all opioid dependent patients aging 20-50 years who were

candidate for orthopedic bone surgery under general anesthesia. Exclusion criteria: patients having the history of cardiovascular disorders; seizure disorder; psychiatric disorder; renal or hepatic dysfunction; taking illicit medications; hypersensitivity to local anesthetic drugs; other anesthetic method and ASA class more than III .

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz Medical School Research Ethic Committee

Street address

3rd Floor, 3rd buiding of the Shiraz Medical School,
Zand Blvd.

City

Shiraz

Postal code

197871345

Approval date

2016-05-09, 1395/02/20

Ethics committee reference number

IR.sums.med.rec.1395.01

Health conditions studied

1

Description of health condition studied

Acute pain

ICD-10 code

R52.0

ICD-10 code description

Acute Pain

Primary outcomes

1

Description

Postoperative analgesia

Timepoint

Every 15 min after patients will become awake in post anesthesia care unit (PACU). During the first 24 h postoperative analgesia will be evaluated every 2 hr for 8 hr then every 4 hr till 24 hr.

Method of measurement

By using Numerical Rating Pain Score (0= No pain,..10= the most severe pain that could imagine)

Secondary outcomes

1

Description

Sedation

Timepoint

every 15 minute in PACU (post anesthesia care unit)

Method of measurement

By using sedation scale: 0 = Restless , 1 = Calm, 2 = Sleepy, 3 = Drowsy with response to verbal stimuli , 4 = Drowsy without response to verbal stimuli, 5 = Without response to painfull stimuli

2

Description

Patients satisfaction

Timepoint

Every 4 hr during first 24 hr post operation

Method of measurement

Patients satisfaction score : 0 = Completely unsatisfied 1 = Unsatisfied 2 = Neutral 3 = Satisfied 4 = Completely satisfied

3

Description

Postoperative nausea and vomiting

Timepoint

Every 4 hr during first 24 hr post operation.

Method of measurement

By using 3-point scale: 0 = no nausea, vomiting, 1 = nausea only, and 2 = retching or/and vomiting

4

Description

Respiratory depression

Timepoint

Every 4 hr during first 24 hr post operation

Method of measurement

Difined as respiratory rate < 8/min

Intervention groups

1

Description

In the group A, after induction of anesthesia, lidocaine will be started with a bolus 1.5 mg/kg followed by infusion 2 mg/kg per hour up to the end of the surgery.

Category

Treatment - Drugs

2

Description

In the group B, after induction of anesthesia, Ketamine will be administered as a 0.5mg/kg bolus, followed by an infusion of 0.2 mg/kg per hour up to end of surgery.

Category

Treatment - Drugs

3

Description

In the control group, after induction of anesthesia, normal saline will be started as a bolus, followed by an infusion up to end of surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Training and Medical Center operation room

Full name of responsible person

Mohammad Ali Sahmeddini

Street address

Operating room, Chamran Training and Medical Center, Chamran Blvd.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery of Research and Technology

Full name of responsible person

Seyed Basir Hashemi

Street address

Shiraz University Of Medical Sciences building, Zand Blvd.

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellery of Research and Technology

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

Shiraz University Of Medical Sciences

Full name of responsible person

Mohammad Ali Sahmeddini

Position

Associate Professor of Anesthesiology

Other areas of specialty/work

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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