# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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

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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**
Repiratory depression

**Timepoint**
Every 4 hr during first 24 hr post operation

**Method of measurement**
Difined as repiratory 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 tp 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
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*