Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

Survey the effect of Ketodex on postoperative pain management of opioid-dependent patients undergoing orthopedic ankle surgery.

Protocol summary

Study aim
The aim of the present study is to investigate the effect of Ketodex on postoperative pain intensity in opioid-dependent patients undergoing orthopedic ankle surgery

Design
This study will be done in the operating room. All of the drugs solution (Ketodex and placebo) of this study will be prepared by only one person who is aware of the study's grouping, in 50 ml syringes in the same shape. Anesthesiologist, patients, and all medical staff that will collaborate in the study will not aware of the drug allocated to each patient.

Settings and conduct
In the present double-blind clinical trial, which will be carried out in a parallel way, a total of 60 opioid-dependent patients who will be undergoing orthopedic ankle surgery under general anesthesia will be enrolled. Eligible patients will be randomly allocated into two equal A and B groups by block randomization.

Participants/Inclusion and exclusion criteria
Inclusion criteria: all opioid-dependent patients who will be undergoing orthopedic ankle surgery under general anesthesia. Non-inclusion criteria: the history of cardiovascular disorders; seizure; brain tumor; taking illicit drugs; psychologic disorder and patient has ASA class III or more.

Intervention groups
Intervention group: for patients in group A, ketodex infusion will be started (Ketamine 0.1mg/Kg/min and dexmedetomidine 0.1 mic/Kg/min) through a 50 ml syringe with the label A after induction of anesthesia till the end of surgery. Control group: patients in this group will receive IV infusion of physiologic saline with a 50 ml syringe with the label B during surgery.

Main outcome variables
Postoperative pain; intraoperative hemodynamic parameters; postoperative sedation, and nausea & vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121204011662N15**
Registration date: **2020-12-03, 1399/09/13**
Registration timing: **prospective**

Last update: **2020-12-03, 1399/09/13**
Update count: **0**

Registration date
2020-12-03, 1399/09/13

Registrant information

Name
Mohammad Ali Sahmeddini

Name of organization / entity
Shiraz University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-05, 1399/09/15

Expected recruitment end date
2021-12-06, 1400/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Survey the effect of Ketodex on postoperative pain management of opioid-dependent patients undergoing orthopedic ankle surgery.

Public title
Survey the effect of mixture of two anesthetic drugs on control of postoperative pain of opioid dependent patients undergoing orthopedic ankle surgery.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All opioid dependent patients who will be candidate for orthopedic ankle surgery under general anesthesia.

Exclusion criteria:
Patients with history of cardiovascular disorders Patients with history of seizure disorder Patients with history of brain tumor Patients with history of taking illicit medications Patients with history of psychologic disorder If general anesthetic will not be used. If patient has ASA class III or more.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly allocated into two groups by block randomization. In this technique, a permutation block of size 4 will be made for patients of two groups A & B. In each block, equal numbers for two groups will be considered in alternative positions. Then 15 blocks of size 4 will be selected randomly and patients will be allocated randomly and equally into three groups according to these permutation block.

Blinding (investigator's opinion)
Double blinded

Blinding description
For blindness, All of the drugs solution (ketodex and normal saline) of this study will be prepared in 50 ml syringes that are similar and equal in shape, by a nurse of anesthesia who is aware of patients' grouping. These syringes will have labels A or B. An anesthesiologist who will use these syringes will not aware of the content of these syringes, and just will use syringes with label A for patients in group A and syringes with label B for patients in group B. Patients and all medical staffs who will collaborate in data gathering, will not be aware of the content of these syringes.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz Medical School

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

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Shiraz

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197871345

Approval date
2020-10-13, 1399/07/22

Ethics committee reference number
IR.SUMS.MED.REC.1399.424

Health conditions studied

1

Description of health condition studied
Acute pain

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural 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 Ramsay sedation score: 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

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

3

Description

Mean arterial blood pressure (MAP)

Timepoint

Values will record every 15 minutes till end of surgery.

Method of measurement

Non invasive blood pressure monitoring.

4

Description

Heart rate per minute

Timepoint

Values will record every 15 minutes till end of surgery.

Method of measurement

Electrocardiogram

Intervention groups

1

Description

Intervention group: patients in group A, Ketodex infusion (Ketamine 0.1mg/Kg/min and Dexmedetomidine 0.1 mic/Kg/min) will be started through a 50 ml syringe with the label A after induction of anesthesia till the end of surgery.

Category

Treatment - Drugs

2

Description

Control group: after induction of anesthesia, patients in group B will received intravenous infusion of the normal saline through a 50 ml syringe with the label B till end of surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Training and Medical Center operation room

Full name of responsible person

Mohammad Ali Sahmeddini

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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

98-01-01-21541

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available