Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of opioid sparing effect of low dose ketamine vs. dexmedetomidine in opioid abusers undergoing laparascopic nephrectomy

Protocol summary

Summary

Aim: To compare opioid-sparing effect of pre-emtive low dose ketamine vs. loading and infusion dose of dexmedetomidine in opioid abusers. Patients: one hundered opioid abusers (daily oral application of opium and/or methadone for the the last 6 weeks for non-medical purposes),undergoing laparascopic nephrectomy. Method: After taking IRB and written informed consent, patients were randomly allocated into two groups. group K received 0.1 mg/kg bolus intravenous ketamine while in group D patients receive 0.5 mic/kg dexmedetomidine in 10 minutes before start of anesthesia and its infusion (0.1 mic/kg/h) continiued till the end of surgery.Both groups received same protocol of anesthesia with propofol and remifentanil and postoperatively PCA applied for 24 hours. Measurement:Total amount of remifentanil (to maintain MAP within 20% range of its base) and postoperative opioid analgesia requirements (in the first 24 hours) were assessed as primary outcome. Discharge time from recovery, bradypnea, apnea, vomiting, itching, hemodynamic instability (changes of MAP or PR more than 30% lasting more than 5 minutes) were evaluated as secondary outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307203436N3**
Registration date: **2013-08-03, 1392/05/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-08-03, 1392/05/12

Registrant information

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Babak Gharaei
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Recruitment status

Recruitment complete

Funding source

Anesthesiology Research Center, Labbafinejad Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of opioid sparing effect of low dose ketamine vs. dexmedetomidine in opioid abusers undergoing laparascopic nephrectomy

Public title

Dexmedetomidine vs ketamine to reduce analgesia requirement in opioid addicts

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion: 1- ASA physical status I or II 2- No probability for difficult airway 3- No allergy to remifentanil, ketamine, propofol or dexmedetomidine 4- No alcohol, tranquilizer or intravenous drug abuse 5- No cognitive or memory disorder 6- No history for hypertension, Increased ICP, present pregnancy or psychiatry disorder Exclusion: 1- surgery lasts more than 4 hours 2- Mean arterial pressure (MAP) change greater than 30 % lasting more than 5 minutes 3- Pulse rate change greater than 30% lasting more than 5 minutes 4- Application of drugs not mentioned in the protocol (however data is recorded)

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Velenjak

City

Tehran

Postal code

Approval date

2012-12-10, 1391/09/20

Ethics committee reference number

400-9491

Health conditions studied

1

Description of health condition studied

opioids abuse

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description

post operative morphine requirement

Timepoint

(post intervention) 24 h postoperative

Method of measurement

mg

2

Description

Intra-operative remifentanil requirement

Timepoint

(during and post intervention) during surgery

Method of measurement

micrigram

Secondary outcomes

1

Description

Bradypnea (RR less than 8/min)

Timepoint

(after intervention) recovery

Method of measurement

pulse oximetry

2

Description

apnea (central apnea for more than 10 sec)

Timepoint

(after intervention) recovery

Method of measurement

Observation

3

Description

itching (post-operative complaint of patient)

Timepoint

(after intervention) recovery and 24 h post-operatively

Method of measurement

Observation

4

Description

Recovery discharge time

Timepoint

(after intervention) recovery

Method of measurement

minutes from arrival to discharge

5

Description
Hemodynamic instability
Timepoint
(during and after intervention) under anesthesia
Method of measurement
blood pressure and heart rate every 5 minutes (recording)

Intervention groups

1

Description
Intervention: Pre-emptive bolus intravenous ketamine (0.1 mg/kg) with normal saline infusion (similar to other group for blinding)
Category
Prevention

2

Description
Intervention: Intravenous dexmedetomidine (0.5 mic/kg in 10 min as loading then 0.1 mic/kg/h till the end of surgery) one bolus normal saline for blinding
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Labbafinejad Hospital
Full name of responsible person
Babak Gharaei
Street address
9th Boostan, Pasdaran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Anesthesiology Research Center, Labbafinejad Hospital, Shahid Beheshti University of Medical Science
Full name of responsible person
Homayoun Aghamohammadi
Street address
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Anesthesiology Research Center, Labbafinejad Hospital, Shahid Beheshti University of Medical Science
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
Anesthesiology Research Center, Labbafinejad Hospital, Shahid Beheshti University of Medical Science
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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