Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of the effect of adding ketamine in dose reduction of morphine with PCA pump in postoperative analgesia after major abdominal surgery

Protocol summary

Summary

Patients undergoing major abdominal surgery experience severe pain postoperatively. They usually require more opioid analgesic consumption and long-term hospital stay, which consequently result in higher costs. Thus, in this double-blinded, randomized controlled clinical trial we investigated if the addition of ketamine to morphine with patient-controlled analgesia (PCA) pump will result in improved analgesic efficacy and lower pain scores and consequently lower doses of opioids compared with morphine PCA alone after major abdominal surgery. In this study, 115 patients with baseline analgesic consumption of 1 gr Paracetamol every 6 hours, were randomly allocated to receive either morphine 0.02 mg/kg (Group M) or morphine 0.02 mg/kg plus ketamine 0.25 mg/kg (Group MK) after a primary bolus 0.04 mg/kg dose of morphine delivered via PCA. The postoperative pain will be assessed by VAS (visual analog scale) at the time of stay in the ward, during the first 48 hours in precise intervals. Also, the patients' demographic data such as age and gender, the dose and kind of analgesic will be documented.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112128384N1**
Registration date: **2012-05-31, 1391/03/11**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-05-31, 1391/03/11

Registrant information

Name

Arash Peivandi Yazdi

Name of organization / entity

Mashhad University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-10-21, 1391/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of adding ketamine in dose reduction of morphine with PCA pump in postoperative analgesia after major abdominal surgery

Public title

Evaluation of the effect of adding ketamine in dose reduction of morphine with patient-controlled analgesia pump in postoperative analgesia after major abdominal surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: • Adult patients who undergo midline laparotomy Exclusion Criteria • Patients with pain disorder • Consumption of any narcotics and analgesics

within a week before surgery • Narcotics addicts • Any contraindication in consumption of paracetamol, morphine or ketamine • Consumption of psychotropic drugs • Any non-midline incision or below umbilicus incisions • Surgical procedures with pelvic tissue manipulation • Noncompliant patients

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **115**

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
Mashhad University of Medical Sciences

Street address
Ghoreyshi Building, Daneshgah Street

City
Mashhad

Postal code

Approval date
2011-02-18, 1389/11/29

Ethics committee reference number
900418

Health conditions studied

1

Description of health condition studied
Pain after abdominal surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain Intensity

Timepoint
Every 2 hours for 6 hours and then every 6 hours up to 48 hours

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Delirium

Timepoint
During the first 48 hours at ward post operatively

Method of measurement
ICU_CAM scale

2

Description
Pain location

Timepoint
During the first 48 hours at ward post operatively

Method of measurement
Subjectively by patient

3

Description
Morphine side effects-Nausea

Timepoint
Within the first 24 hours after intervention

Method of measurement
Times of nausea

4

Description
Morphine side effects_Respiratory suppression

Timepoint
Within the first 48 hours after intervention

Method of measurement
Respiratory rate

5

Description
Incision location

Timepoint
After operation

Method of measurement
Anatomical description

6

Description
Operating time

Timepoint
Duration between induction and end of general

anaesthesia
Method of measurement
Minutes

7

Description
Reason for surgical procedure
Timepoint
After operation
Method of measurement
Benign_Malignant, Explorative, Acute_Chronic, NOS

Intervention groups

1

Description
Adding intravenous ketamine to Morphine PCA in MK group
Category
Treatment - Drugs

2

Description
Only Morphine PCA to control group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Surgical Oncology Research Center
Full name of responsible person
Dr. Arash Peivandi Yazdi
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
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Vice Chancellor for Research, Ghoreyshi Building, Daneshgah Street
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
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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