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: empty
Update count: 0
Registration date: 2012-05-31, 1391/03/11

Registrant information
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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
None
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 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 Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences
Street address
Ghorayshi 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
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
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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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

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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