

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Effect of adding ketamine to fentanyl patient-controlled analgesia for postoperative pain after laparotomy

Protocol summary

Summary

The aim of this study is the assessment of ketamine adding to fentanyl in IV-PCA pumps for control of postoperative pain after laparotomy surgery in the general operating theaters of Hazrat Rasul Akram Hospital. The inclusion criteria are: 100 Patients age between 20- 60 years, who candidate for abdominal surgery, ASA physical status class I & II, Exclusion criteria are: 1 - Substance and alcohol abuse 2 - Chronic pain or daily intake housing 3 - Those who do not cooperate 4 - A history of seizures 5 - Liver dysfunction or abnormal liver enzymes 6 - Sensitivity to drugs The anesthesia technique is the same for patients of two groups. For induction of anesthesia, thiopental 5 mg/kg, cisatracurium 0.2 mg/kg and remifentanyl 1 µg/kg will be used. For maintenance of anesthesia, propofol 100µg/kg/min and remifentanyl 1 µg/kg/min and repeated 2 mg cisatracurium shall be used every 30 minutes. Patients will be divided randomly into two groups. In group 1 the IV PCA Pump will be filled with 0.01 mg/ml fentanyl and 0.5 mg/ml ketamine and in group 2 only 0.01 mg/ml fentanyl will be used in pumps. The pumps will be connected to patients in recovery room before exacerbation of pain, maximally up to 2 hours after the end of operation. Then the severity of pain according to VAS will be assessed every 6 hours upto 48 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT20111128075N1**
Registration date: **2012-03-27, 1391/01/08**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-03-27, 1391/01/08

Registrant information

Name

Minoos Sedaghat

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-04-01, 1391/01/13

Expected recruitment end date

2012-07-01, 1391/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of adding ketamine to fentanyl patient-controlled analgesia for postoperative pain after laparotomy

Public title

ketamine effect for pain relief after abdominal surgery

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: 100 Patients age between 20- 60 years, who candidate for abdominal surgery, ASA

physical status class I & II, Exclusion criteria: 1 - Substance and alcohol abuse 2 - Chronic pain or daily intake housing 3 - Those who do not cooperate 4 - A history of seizures 5 - Liver dysfunction or abnormal liver enzymes 6 - Sensitivity to drugs

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

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

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

school of medicine P.O.BOX : 14155-6447

City

Tehran

Postal code

1417613151

Approval date

2011-12-05, 1390/09/14

Ethics committee reference number

42113

Health conditions studied

1

Description of health condition studied

cholelithiasis

ICD-10 code

K-80.0

ICD-10 code description

Calculus of gallbladder with acute cholecystitis

2

Description of health condition studied

noneinflammatory disorders of ovary

ICD-10 code

N-83.0

ICD-10 code description

Follicular cyst of ovary

Primary outcomes

1

Description

Pain

Timepoint

Every 6 hours until 48 hours after surgery

Method of measurement

VAS (visual analogous scale)

Secondary outcomes

empty

Intervention groups

1

Description

In group 1 the IV PCA Pump will be filled with 0.01 mg/ml fentanyl and 0.5 mg/ml ketamine.

Category

Treatment - Drugs

2

Description

In group 2 only 0.01 mg/ml fentanyl will be used in pumps.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

General operating theaters of Hazrateh Rasul Akram Hospital

Full name of responsible person

Dr Minow Sedaghat

Street address

Sattar-Khan Ave., Niayesh St

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice- Chancellor for Research of Tehran University of Medical Sciences

Street address

Keshavarz Boulevard, Qods Ave- Central Organization of Tehran University of Medical Sciences- 4th Floor

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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****Name of organization / entity**

Hazrateh Rasul Akram Hospital, Tehran University of Medical Sciences

Full name of responsible person

Dr Minow Sedaghat

Position

MD, Anesthesiologist resident

Other areas of specialty/work**Street address**

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Web page address**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