

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: **IRCT201111128075N1**
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

+98 21 6655 7141

Email address

m-sedaghat@razi.tums.ac.ir

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**

Satar khan Ave. Niayesh st.

City

Tehran

Postal code

14455364

Phone

+98 21 6435 2326

Fax

+98 21 6650 9059

Emailm-sedaghat@razi.tums.ac.ir;
sedaghat1357@gmail.com**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hazrateh Rasul Akram Hospital, Tehran University of Medical Sciences

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Emailm-sedaghat@razi.tums.ac.ir;
sedaghat13578@gmail.com**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*