Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparision of the effects of adding ketamin or ketorolac to fentanyl for intravenous patient-controlled analgesia on postoperative pain after abdominal hysterectomy

Protocol summary

Summary

The purpose of this study is to evaluate the effects of adding ketamin or ketorolac to fentanyl for intravenous patient-controlled analgesia on postoperative pain in the women undergoing general anesthesia for abdominal hysterectomy in Shahid Sadoughi hospital in Yazd, Iran. In this randomized double blind trial, 60 women, aged 40-60 years old, and ASA physical status I and II, were assigned into one of the following two groups to receive ,ketamine 0.5 mg/ml or ketorolac 0.6 mg/ml adding to fentanlyl 5 µg/ml via intravenous patient-controlled analgesia after the surgery. Postoperative pain was assessed through visual analog scale (VAS) at 2, 6, 12, and 24 hours after the surgery. Side effects of study drugs (nausea,vomitting,respiratory depression and hallucination) were evaluated during 24 hours and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409132963N20**
Registration date: **2015-01-08, 1393/10/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-01-08, 1393/10/18

Registrant information

Name

Shekoufeh Behdad

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-03-16, 1393/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of the effects of adding ketamin or ketorolac to fentanyl for intravenous patient-controlled analgesia on postoperative pain after abdominal hysterectomy

Public title

Comparision of the effects of adding two drugs to an opium for intravenous patient-controlled analgesia on postoperative pain after abdominal surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women with American Society of Anesthesia (ASA) physical status I or II who are candidate for elective abdominal hysterectomy, age 40-60 years old Exclusion criteria: patients with BMI>35 and a history of mental impairment,chronic pain,allergic reactions to the study drugs,addiction were excluded.

Age
From **40 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
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 Sadoughi University of Medical Sciences
Street address
Bahonar square
City
Yazd
Postal code
Approval date
2014-09-10, 1393/06/19
Ethics committee reference number
9630

Health conditions studied

1

Description of health condition studied
ketamine
ICD-10 code
Y48.4
ICD-10 code description
Anaesthetic, unspecified

Primary outcomes

1

Description
postoperative pain
Timepoint
2,6,12,24 hours postoperatively
Method of measurement
visual analog pain score

Secondary outcomes

1

Description
side effects(respiratory depression,nausea,vomiting,Hallucination)
Timepoint
2, 6, 12 and 24 hours after operation
Method of measurement
asking the patient, physical examination

Intervention groups

1

Description
in the first group ketamine 0.5 mg/ml is added to fentanlyl 5 µg/ml via intravenous patient-controlled analgesia
Category
Treatment - Drugs

2

Description
in the second group ketorolac 0.6 mg/ml is added to fentanlyl 5 µg/ml via intravenous patient-controlled analgesia
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital
Full name of responsible person
Street address
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadoughi University of Medical Science
Full name of responsible person
Dr. Hasan Mozaffari
Street address
Bahonar square
City
Yazd

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadoughi 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

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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