

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of fentanyl and ketorolac with PCA pump for post abdominal hysterectomy pain control

Protocol summary

Summary

The purpose of this study is the comparison of fentanyl and ketorolac with PCA (patient controlled analgesia) pump for post abdominal hysterectomy pain control
Inclusion criteria: 108 patients 20 to 60 years old; ASA I,II
Exclusion criteria: Allergic reaction to Fentanyl or ketorolac Patients were divided into two groups randomly; the first group receives Fentanyl with PCA Pump and the second group receive Ketorolac with PCA pump the last half hour surgery . then the pain evaluate by VAS(visual analogue scale),The heart rate, respiratory rate, and mean arterial pressure, and sedation score are recorded at 1, 6, 12, 24 hours postoperative.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503288677N5**
Registration date: **2015-07-09, 1394/04/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-09, 1394/04/18

Registrant information

Name

Farnoush Farzi

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of fentanyl and ketorolac with PCA pump for post abdominal hysterectomy pain control

Public title

The comparison of fentanyl and ketorolac with PCA pump for post abdominal hysterectomy pain control .

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:Age 20 to 60 years old; ASA I,II
Exclusion criteria: Allergic reaction to Fentanyl or ketorolac

Age

From **20 years** old to **65 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

N/A

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

Ethics committee of Guilan University of Medical Sciences

Street address

Shahid Beheshti Freeway

City

Rasht

Postal code

4193893345

Approval date

2015-02-24, 1393/12/05

Ethics committee reference number

1930596733

Health conditions studied

1

Description of health condition studied

Hysterectomy

ICD-10 code

O82.2

ICD-10 code description

Delivery by caesarean hysterectomy

Primary outcomes

1

Description

Pain

Timepoint

Baseline ,6 and 12 weeks aftersurgery

Method of measurement

Visual Analog score

2

Description

Sedation

Timepoint

1,6,12,24 hours after surgery

Method of measurement

Sedation score

Secondary outcomes

empty

Intervention groups

1

Description

The first group of pain pumps containing 100 cc (750 mcg of Fentanyl and time-consuming saline) at a rate of 0.4µg / kg / h infusion of Fentanyl that of 30 minutes before the end of the surgery starts.pump started 30 minutes before the end of surgery

Category

Prevention

2

Description

Pain pump in the second group contained 100 cc (90 mg Ketorolac 30mg/ml time-consuming saline) speed 0.05 Ketorolac 30mg/ml in half an hour before surgery begins. Ketorolac 30mg/ml mg / kg / h, Produced by :Iran hormone factory

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Farnoush Farzi

Street address

Namjoo Street

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Guilan University of Medical Sciences

Full name of responsible person

Abtin Heidarzadeh

Street address

Shahid Beheshti Freeway

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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

Vice chancellor for research of Guilan 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**

Guilan University of Medical Sciences

Full name of responsible person

Farnoush Farzi

Position

Anesthesiologist

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

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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