

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Comparison 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 fentanyl 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 1822 1386

##### Email address

drbehdad@ssu.ac.ir

##### 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

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

##### Public title

Comparison 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 fentanyl 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 fentanyl 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

### Contact

**Name of organization / entity**  
Shahid Sadoughi University of Medical Sciences  
**Full name of responsible person**  
Dr. Shekoufeh Behdad  
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Associate Professor  
**Other areas of specialty/work**  
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+353 8224105  
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behdad90@gmail.com  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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*