

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the effect of ketorolac and paracetamol on post operative pain in patients undergoing lower limb orthopedic surgery

Protocol summary

Summary

The aim of this study is comparing the effects of Ketorolac and Paracetamol on post-operative pain in lower limbs orthopedic surgeries. This is a randomized double blind clinical trial on 96 patients who are candidate of lower limbs surgery. Inclusion criteria: ASA classification I and II; age 18 to 65 years. Exclusion criteria: pregnancy; history of heart failure; kidney diseases; coagulation disorders; uncontrolled blood pressure. In this study 96 patients are included which be divided in 3 groups by simple sampling method (using randomized numbers table). The patients and observers (researchers) are blind to groups' members. The participants are become familiar with the principle of visual analogue scale (VAS). The VAS of patient is evaluated before induction of anesthesia. The method of anesthesia is similar for all groups. Ten minutes before induction 30 mg ketorolac, 1gr paracetamol and, normal saline is administered in group 1, 2 and 3 respectively. In order to inhibition of narcotics interference with patient's VAS in recovery room, no administration of fentanyl is done, 30 minutes to the end of anesthesia. In recovery room, VAS of the patient is obtained 45 minutes after patient's consciousness. At the end of recovery period, the scores of VAS with all demographic information of the patients in all groups are documented and analyzed by statistic software and the effect of ketorolac and paracetamol on post-operative pain in lower limb surgeries is compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080712007N3**

Registration date: **2015-08-23, 1394/06/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-23, 1394/06/01

Registrant information

Name

Mohammad Reza Doroudian

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1246 2055

Email address

mdoroudian@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Kerman University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of ketorolac and paracetamol on post operative pain in patients undergoing lower limb orthopedic surgery

Public title

Comparison of ketorolac and paracetamol on post operative pain in orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA classification of I and II; age 18 to 65 years. Exclusion criteria: opioids and narcotics abuse for a long time; steroids consumption; pregnancy; history of heart, liver and kidney failure; coagulation disorders; uncontrolled hypertension; endocrine disorders (diabetes); BMI higher than 40; alcoholism; heart rate less than 40 b/m; surgical procedure up to 2 hours; asthma; GI bleeding.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **96**

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**

Ethics committee of Kerman University Medical Sciences

Street address

Shafa Square

City

Kerman

Postal code**Approval date**

2015-01-31, 1393/11/11

Ethics committee reference number

IR.KMU.REC.1394.122

Health conditions studied**1****Description of health condition studied**

postoperative pain

ICD-10 code

M79.6

ICD-10 code description

Pain in limb

Primary outcomes**1****Description**

Pain

Timepoint

45 minutes after consciousness

Method of measurement

VAS (visual analogue scale)

Secondary outcomes**1****Description**

heart rate

Timepoint

every 15 minutes

Method of measurement

automatic monitoring device

2**Description**

Blood pressure

Timepoint

Every 15 minutes

Method of measurement

Automatic monitoring device

Intervention groups**1****Description**

One group will receive 1 gr intravenous paracetamol in 500 cc normal saline 10 minutes before induction of anesthesia

Category

Treatment - Drugs

2**Description**

Second group will receive 30 mg intravenous ketorolac in 500 cc normal saline

Category

Treatment - Drugs

3**Description**

In control group 500 ml normal saline will be given 10 minutes before induction of anesthesia

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahonar Hospital

Full name of responsible person

Anis bahrami

Street address

Baghemelli Square

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Kerman University of
Medical Sciences

Full name of responsible person

Fatemeh Hassani

Street address

Tahmasbabad Square, Ebnesina Street

City

Kerman

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 Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Anis Bahrami

Position

Assistant of anesthesiology

Other areas of specialty/work

Street address

Afzalipoor Hospital, Zendan Square

City

Kerman

Postal code

Phone

+98 34 1223 5011

Fax

Email

anis_bahrami@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Hosseyh Sattari

Position

Anesthesiologist

Other areas of specialty/work

Street address

Bahonar Hospital, Baghemelli square

City

Kerman

Postal code

Phone

+98 34 3223 5011

Fax

Email

hosattari@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Anis Bahrami

Position

Assistant of anesthesiology

Other areas of specialty/work

Street address

Afzalipoor Hospital, Zendan Square

City

Kerman

Postal code

Phone

+98 34 1223 5011

Fax

Email

anis_bahrami@yahoo.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